South Dakota Critical Access Hospital Program

(SoDaCAHP)

RURAL HEALTH PLAN

South Dakota Department of Health
Division of Health Systems Development and Regulation
Office of Rural Health

May 2006

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Doneen B. Hollingsworth, Secretary of Health

Pierre, South Dakota
May 2006
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FORWARD

The South Dakota Rural Health Plan is to be used by the State of South Dakota in administering the Medicare Rural Hospital Flexibility Program (MRHFP) pursuant to section 4201 of the Balanced Budget Act of 1997 (Public Law 105-33) and amendments made thereto. The points of contact for the South Dakota Critical Access Hospital Program Plan are the following:

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The Office of Rural Health also wishes to thank all the South Dakota Critical Access Hospital Administrators who have provided assistance with the development of the Plan.

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A. INTRODUCTION

1. Background and Purpose

The South Dakota Critical Access Hospital Program (SoDaCAHP) represents the latest in a series of programs undertaken as part of a state rural hospital initiative that began in 1990. In the summer of that year a Governor's Conference on Rural Health was convened. The Conference, which attracted a large audience, identified prevention of rural hospital closure as the number one rural health priority in the state.

Subsequent to the Conference, the Department of Health initiated a number of programs to assist rural hospitals, including application to be one of the seven states included in the Medicare Essential Access Community Hospital/Rural Primary Care Hospital (EACH/RPCH) Program. Under that program, nine RPCHs in seven networks were designated and certified for participation. Eight of the RPCHs participate in the MRHFP as certified CAHs.

The hospital industry has undergone significant changes in the past decade. Many of these changes have been beneficial and have helped to maintain or strengthen access while controlling costs. On the other hand, there is concern that certain regulatory measures, combined with changes within the hospital marketplace could lead to loss of hospital services in areas where access to health care would otherwise be diminished. The purpose of SoDaCAHP is simply to help maintain access to essential health services by offering certain rural hospitals an alternative approach. This approach offers a degree of regulatory flexibility and cost-based reimbursement in exchange for limitations on the amount of inpatient services available.

The SoDaCAHP Rural Health Plan represents one approach to maintaining and improving the health of South Dakotans. Effects of the SoDaCAHP will be different for each hospital, depending on a number of factors. Facilities interested in the Program will want to carefully weigh as many variables as possible to determine whether participation suits their needs.

2. Definitions

"Applicant" - a facility which applies to the Office of Rural Health, Department of Health for designation as a Critical Access Hospital.

"CAH Network or Network" - an affiliation or grouping of facilities/services as witnessed by certain written agreements between at least one Critical Access Hospital and one Referral Hospital. The purpose of a networks is to broaden services, increase quality and create cost efficiencies.

"Certification" - a process leading to formal recognition by the Centers for Medicare and Medicaid Services of a licensed hospital meeting Medicare Conditions of Participation as a Critical Access Hospital.

"Designation" - official finding and recognition by the Department of Health that both a prospective Critical Access Hospital and its hospital network have met requirements for state designation and intend to meet state and federal eligibility requirements for state licensure and

Medicare certification as a Critical Access Hospital, within a certain time period. Designation does not infer Medicare certification.

"Eligible hospital" - a nonprofit or public facility licensed by the state of South Dakota as a general or specialized hospital, which is located in a rural area as defined by CMS or the state of South Dakota and meets the mileage and/or "necessary provider" criteria contained in this plan; or a hospital, which closed after November, 1989 and otherwise meets the stated criteria.

"Office" - the South Dakota Office of Rural Health, Division of Health Systems Development and Regulation, Department of Health.

"Plan" - the SoDaCAHP Rural Health Plan.

"Referral Hospital" - a facility licensed as a general hospital by the state Department of Health and, at a minimum has signed written agreements with the Applicant pertaining to: 1) patient referral and transfer; 2) the development and use of communications systems (if the network has in operation such a system); and 3) the provision of emergency and non-emergency transportation.

B. OVERVIEW

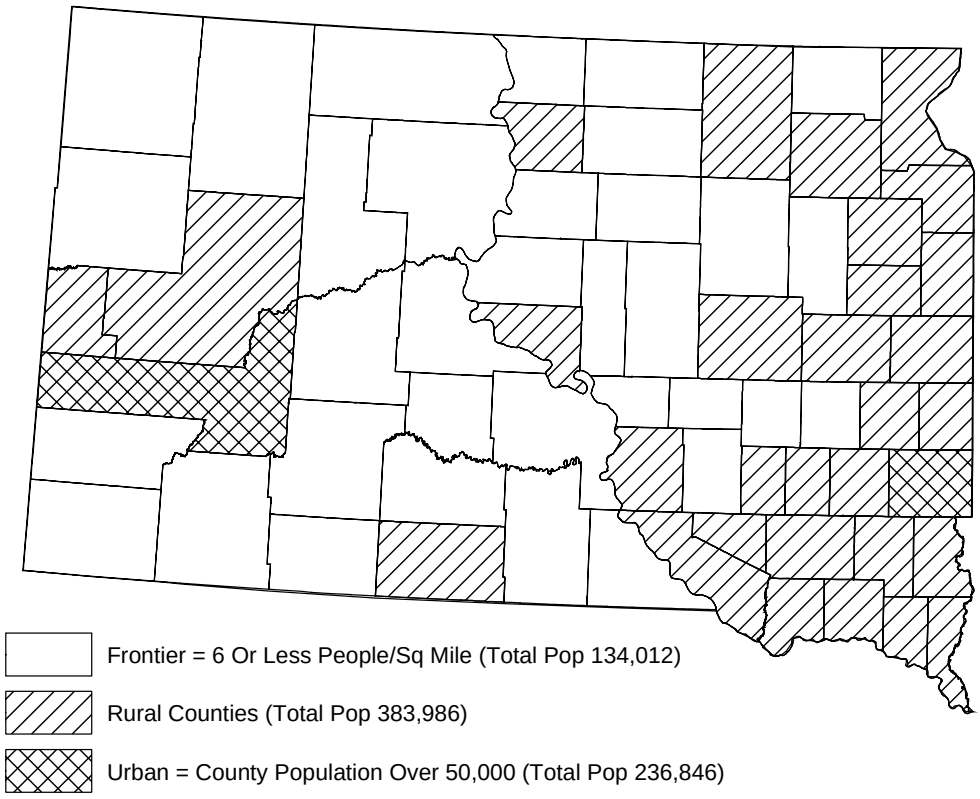
South Dakota is often referred to as being one of the most rural states in the country. Although certainly true, this is a little misleading since the term "rural" is relative. For example, Medicare generally considers any community under 50,000 to be rural. Most South Dakotans, on the other hand, would consider a community of 25,000 to be urban and a community of 10,000 to be fairly large.

It would be more accurate to characterize South Dakota as a frontier state. "Frontier" was a term adopted by the federal government several years ago to characterize areas having 6 or fewer people per square mile. As Figure 1 on the next page shows, 34 of the state's 66 counties are classified as frontier, using this definition.

The distinguishing feature of frontier practice sites is that they are often fragile in the sense that resources used to provide care, such as health professionals or facilities, are few in number. This is not by design, but often a fact of life owing to low utilization levels. Changes in health care utilization or changes in resources such as the loss of a physician can lead to sudden and significant changes in the availability of services.

Regardless of whether South Dakota is characterized as a rural or frontier state, geographic access to health care remains a significant issue. Whereas sparsely populated rural areas present a unique set of problems for the delivery of health services - especially basic services such as emergency and primary care - a measurement of medical under-service is needed to provide an assessment of geographic access. In addition to mileage, federal indicators include Health Professional Shortage Area (HPSA) and Medically Underserved Area (MUA) designations.

FIGURE 1. SD POPULATION DENSITY BY COUNTY, 2000

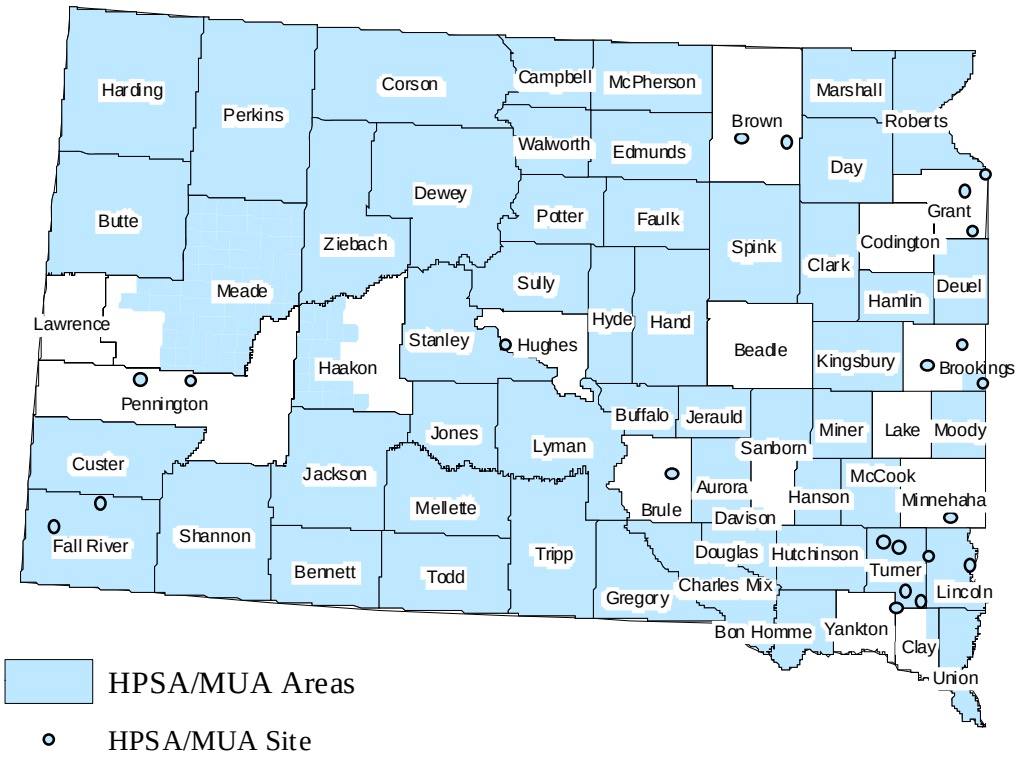


Source: 2000 U.S. Census

The federal Bureau of Primary Health Care makes HPSA and MUA designations. HPSA designation is based on factors such as the ratio of primary care physicians to population within a service area, as well as measurements of access to care in surrounding areas. MUA designation is based on several health status indicators such as poverty rate, age 65 and over, infant mortality, and physician supply. Although some progress has been made in reducing the number of HPSAs in South Dakota, many still remain as Figure 2 on the following page shows.

It is within these shortage areas that the notion of "critical access" to basic health services is of utmost importance. It is the intent of this Plan to help ensure that hospitals located in such areas are afforded the opportunity to participate in the South Dakota Critical Access Hospital Program. **Hence, any rural hospital located in a HPSA or MUA at the time of designation shall be considered to be a "necessary provider".** In addition, it is the intent of this plan that should HPSA or MUA designation be withdrawn for any area within which a designated or certified CAH is located, such designation or certification will continue.

FIGURE 2. HEALTH PROFESSIONAL SHORTAGE AREAS & MEDICALLY UNDERSERVED AREAS
April 15, 2006



Source: Office of Rural Health, South Dakota Department of Health

C. PLAN GOALS AND OBJECTIVES

Goal 1: To provide clear policy direction through development, revision and implementation of one central document (State Rural Health Plan) that can be readily accessed by providers and the public.

Objective 1.1: Monitor changes in applicable federal and state laws, regulations and policies.

Objective 1.2: Update the SoDaCAHP Plan as needed after changes in federal or state laws, regulations, or policies occur.

Goal 2: To assist frontier and rural communities by assessing community needs; examining the appropriate-ness of designation and conversion to the Critical Access Hospital model; and promoting awareness of the program statewide.

Goal 3: To develop sustainable local systems of care by developing networking arrangements which will enhance efficiencies and improve access to care.

Goal 4: To improve the rural emergency medical services system by sponsoring initiatives in the areas of trauma, communications, training and quality enhancement.

Goal 5: To enhance quality of care within Critical Access Hospitals by assisting CAHs in obtaining a qualified workforce, providing opportunities for on the job training and reducing medication errors.

Goal 6: To evaluate the SoDaCAHP by continuing to collect data and soliciting feedback from rural facilities.

D. CRITICAL ACCESS HOSPITAL FACILITY AND NETWORK DESIGNATIONS – POLICIES AND PROCEDURES

1. Criteria for Identification and Designation of Critical Access Hospitals (CAHs) and Critical Access Hospital Networks.

The State must make finding that the hospital petitioning for CAH designation (Applicant) meets the following criteria:

Criterion 1: Eligibility

Standard: The Applicant must be a nonprofit or public hospital located in a rural area of South Dakota. This is defined as either: 1) a county defined by Medicare as rural (or non-MSA); or 2) any municipality of under 3,500 which is situated in a MSA but is more than 15 miles from a city of at least 50,000 population.

Standard: In the case of a closed hospital, the facility must have ceased operations after November 1989.

Criterion 2: Location relative to other facilities or necessary provider certification

Standard: The Applicant must meet one of the following:

a) The CAH is located more than a 35-mile drive from a hospital or another CAH; or

b) In the case of mountainous terrain or in areas with only secondary roads available, the CAH is located more than a 15-mile drive from a hospital or another CAH (Note the Centers for Medicare and Medicaid Services interpretive guidelines to determine mountainous terrain and secondary roads can be found in APPENDIX D); or

c) Before January 1, 2006, the CAH is designated by the State as being a necessary provider of health care services to residents in the area. A CAH that is designated as a necessary provider as of January 1, 2006 will maintain its necessary provider designation after January 1, 2006. A hospital is designated by the State of South Dakota as a necessary provider if it meets one of the following: 1) location of the facility in a current federally designated primary medical care Health Professional Shortage Area (HPSA); 2) location of the facility in a current federally designated Medically Underserved Area (MUA); or 3) the facility is at least 15 road miles from the closest community hospital. (Note: Designated/certified Critical Access Hospitals located in HPSAs /MUAs which are subsequently withdrawn as HPSAs/MUAs shall continue to be recognized as Critical Access Hospitals.)

Criterion 3: Member of a rural health network

Standard: The Applicant shall be a member of a rural health network, as evidenced by signed written agreements with at least one Referral Hospital that is a member of the network. The agreements must pertain to: 1) patient referral and transfer; 2) the development and use of communications systems (if the network has in operation such a system); and 3) the provision of emergency and non-emergency transportation. Such agreements shall be in effect upon submission of an application for designation.

Standard: The Applicant must have a process for credentialing and quality assurance with at least one hospital that is a member of the network or with the South Dakota Foundation for Medical Care (QIO). The process shall be described in a signed written agreement that must be in effect upon submission of an application for designation.

Standard: The rural health network shall have at least one Referral Hospital that has sufficient resources to receive emergency and non-emergency patient transfers and/or referrals from the Applicant. Sufficient resources include: at least three full-time physicians on staff; demonstrated history of accepting patient referrals/transfers from the Applicant; and licensure as a general hospital.

Criterion 4: Emergency services

Standard: The Applicant must make available 24-hour emergency care services, seven days a week, regardless of inpatient census. The applicant must have at least one physician on duty or on call at all times and available to the hospital on-site or by telephone within 20 minutes to give medical care in case of emergency.

Criterion 5: Bed size

Standard: The Applicant must agree to provide not more than 25 licensed beds.

Standard: The Applicant must agree that no more than 15 beds may be designated as swing beds.

Criterion 6: Staffing

Standard: Minimum staffing includes at least one registered nurse if the facility has at least one acute care inpatient, or one licensed nurse if the facility has no acute care inpatients.

Criterion 7: Acute care inpatient length of stay

Standard: The Applicant must agree to provide inpatient care for a period that does not exceed, as determined on an annual, average basis, 96 hours per patient.

Criterion 8: Application for CAH designation

Standard: The Application for Designation Form must be judged as complete and approved by the Secretary of Health.

2. Procedure for CAH and CAH Network Designation

Anyone can request information from the Office of Rural Health relative to the South Dakota Critical Access Hospital Program (SoDaCAHP) at any time. Formal requests for Designation and Certification will be handled as follows:

Step One: Facilities which meet Criteria 1 and 2 contained in this plan must request an "Application For Designation Form" (a copy is in APPENDIX A) in writing from the Office of Rural Health (Office).

Step Two: The Office will, within five working days from receipt of the request, mail the application form, plus other pertinent materials to Applicant. On-site technical assistance will be provided, if requested.

Step Three: The Applicant will have up to six months to complete and submit an application form to the Office. The Applicant can request permission to extend the time period for completion of the application.

Step Four: Once the application has been declared complete, the Office will have ten working days to draft preliminary findings and recommendations for consideration by the Secretary of Health.

Step Five: The Secretary of Health will have ten working days to review the findings and recommendations offered by the Office and provide written notice of designation or denial of designation to the Applicant. The Secretary must designate the Applicant as a Critical Access Hospital and the network as a Critical Access Hospital Network before the Applicant can petition for Medicare certification.

Please note that the above process outlines only minimum requirements for designating facilities as Critical Access Hospitals. It is recommended that each hospital develop a clearly defined strategy which includes additional factors such as: governing board education and involvement, financial feasibility study, hospital and medical staff education, community education and awareness, and a study of potential networking relationships.

E. CRITICAL ACCESS HOSPITAL AND CRITICAL ACCESS HOSPITAL NETWORK CERTIFICATION POLICIES AND PROCEDURES

Step One: Upon receiving notice of Designation, the Applicant must submit a letter of interest to the Office of Licensure and Certification (OLC) requesting a pre-survey packet.

Step Two: The OLC will send the Applicant pre-survey packet, which includes:

- 42 CFR Part 485, Subpart F;
- Appendix W, Survey Tasks and Interpretive Guidelines;
- Appendix V, Antidumping;
- 42 CFR 489, Subpart I, Advance Directives;
- Administrative Rules of South Dakota (Article 44:04 Medical Facilities);
- Hospital Request for Certification in the Medicare/Medicaid Program (Form CMS 1514);

- The website location of the Application for Health Care Providers that will Bill Medicare Fiscal Intermediaries (Form CMS 855A); and
- Application for License to Operate a Hospital.

Step Three: The Applicant must submit to OLC a written request for survey to schedule an on-site survey and return the following completed information:
- Form CMS 1514
- Form CMS 855A, And
- Application for License to Operate a Hospital.

Step Four: Upon receipt of the request for survey and completed items listed in Step Three, the OLC will schedule an on-site survey to be conducted within 60 days.

Step Five: The OLC will contact the Applicant, via letter, two weeks prior to the CAH certification survey date. The OLC includes in the letter a list of materials the Applicant must have available for review at the time of survey.

Step Six: Upon completion of the survey, the OLC submits materials and makes recommendation to the Centers for Medicare and Medicaid Services(CMS) the date of initial certification, one of the following:
- Satisfactory survey – date of exit interview; or
- Deficiencies cited – date Plan of Correction is accepted; or
- Upon Applicant request, a date within 60 days of exit interview.

Step Seven: The CMS reviews the materials submitted and recommendation and assigns new Medicare provider number.

Step Eight: The CMS provides notification to the Applicant, OLC, and ORH as to the effective date of certification.

F. DESIGNATED AND CERTIFIED CRITICAL ACCESS HOSPITALS

A HRSA supported National CAH/Flex Tracking Project has developed the following mutually exclusive categories to determine the status of rural hospitals in the CAH program.

Certified: The number of hospitals that have been certified as CAHs by CMS.

Pending: The number of hospitals currently awaiting CAH designation and/or certification.

Candidate: (**Hospitals Actively Considering Conversion)** The number of hospitals that, in the opinion of the state MRHFP grantee, are likely to consider conversion. The Federal Office of Rural Health Policy suggests inclusion, at a minimum, of all hospitals with an Average Daily Census of 7 or less and that have an operating margin of less than 2%; however, ultimate discretion is left to the state program coordinator.

Declined: The number of hospitals that have received substantive support, but have declined to convert to CAH at this time.

Eligible: The number of non-CAHs that meet states' CAH eligibility criteria. Includes all other hospitals that are eligible for conversion which are not counted in the categories above.

The table below shows how South Dakota rural hospitals fit into these categories. For the certified CAHs, it also shows if they meet the 35-mile location criteria or if they were certified as necessary providers.

TABLE 1. STATUS OF SD RURAL HOSPITALS IN THE CAH PROGRAM AS OF JANUARY 1, 2006

Hospital Name	City	Location Criteria	CAH Cert Date	CAH Status
Faulk County Memorial Hospital	Faulkton	35-Mile	03/01/1998	Certified
Platte Comm Memorial Hospital	Platte	Necess Provider	04/01/1998	Certified
Douglas County Memorial Hospital	Armour	Necess Provider	06/01/1998	Certified
Eureka Community Hospital	Eureka	Necess Provider	06/01/1998	Certified
Community Memorial Hospital	Burke	Necess Provider	07/01/1998	Certified
Gettysburg Medical Center	Gettysburg	Necess Provider	07/01/1998	Certified
Deuel County Memorial Hospital	Clear Lake	Necess Provider	10/01/1998	Certified
Five Counties Hospital	Lemmon	Necess Provider	10/01/1998	Certified
Flandreau Municipal Hospital	Flandreau	Necess Provider	01/01/1999	Certified
Lake Area Hospital	Webster	35-Mile	05/01/1999	Certified
Marshall County Memorial Hospital	Britton	35-Mile	03/01/2000	Certified
Freeman Community Hospital	Freeman	Necess Provider	06/01/2000	Certified
Bennett County Community Hospital	Martin	35-Mile	07/01/2000	Certified
Community Memorial Hosp	Redfield	35-Mile	07/01/2000	Certified
Wagner Community Mem Hospital	Wagner	Necess Provider	07/01/2000	Certified
Landmann-Jungman Memorial Hospital	Scotland	Necess Provider	10/01/2000	Certified
Bowdle Hospital	Bowdle	Necess Provider	01/01/2001	Certified
Hans P Peterson Mem Hospital	Philip	35-Mile	02/01/2001	Certified
Lead-Deadwood Regional Hospital	Deadwood	Necess Provider	05/01/2001	Certified
Sturgis Regional Hospital	Sturgis	Necess Provider	05/01/2001	Certified
Fall River Health Services	Hot Springs	Necess Provider	06/27/2001	Certified
Custer Regional Hospital	Custer	Necess Provider	07/01/2001	Certified
Weskota Memorial Medical Center	Wessington Springs	35-Mile	10/01/2001	Certified
Milbank Area Hospital Avera Health	Milbank	Necess Provider	01/01/2002	Certified
Mobridge Regional Hospital	Mobridge	35-Mile	01/01/2002	Certified
St. Michael's Hospital	Tyndall	Necess Provider	03/01/2002	Certified
Pioneer Memorial Hospital	Viborg	Necess Provider	03/01/2002	Certified
Madison Community Hospital	Madison	Necess Provider	12/01/2002	Certified
Mid-Dakota Hospital	Chamberlain	35-Mile	05/01/2003	Certified
Dells Area Health Center	Dell Rapids	Necess Provider	07/01/2003	Certified
De Smet Memorial Hospital	DeSmet	Necess Provider	07/01/2003	Certified
Avera St. Benedict Health Center	Parkston	Necess Provider	07/01/2003	Certified

TABLE 1. STATUS OF SD RURAL HOSPITALS IN THE CAH PROGRAM AS OF JANUARY 1, 2006 (Continued)

Hospital Name	City	Location Criteria	CAH Cert Date	CAH Status
Canton-Inwood Memorial Hospital	Canton	Necess Provider	12/01/2003	Certified
Winner Regional Healthcare Ctr	Winner	Necess Provider	04/01/2004	Certified
Huron Regional Medical Center	Huron	Necess Provider	07/01/2004	Certified
Sioux Valley Vermillion Campus	Vermillion	Necess Provider	11/01/2004	Certified
Hand County Memorial Hospital	Miller	35-Mile	07/01/2005	Certified
Avera Gregory Healthcare Center	Gregory	Necess Provider	12/22/2005	Certified
Avera St. Luke's Hospital	Aberdeen			Eligible
Brookings Hospital	Brookings			Eligible
Holy Infant Hospital	Hoven			Eligible
Avera Queen of Peace Hospital	Mitchell			Eligible
St. Mary's Hospital	Pierre			Eligible
Coteau Des Prairies Hospital	Sisseton			Eligible
Spearfish Regional Hospital	Spearfish			Eligible
Prairie Lakes Hospital	Watertown			Eligible
Sacred Heart Health Services	Yankton			Eligible

A map of South Dakota Community Hospitals is shown in APPENDIX B.

G. TECHNICAL ASSISTANCE AVAILABLE

Hospitals considering designation as Critical Access Hospitals, or facilities that have been designated and/or certified but desire assistance are welcome to contact the State Office of Rural Health. Examples of types of assistance include:

1. To support and help sustain existing CAHs.

- Educational workshops are provided to CAH Administrators and other staff on topics such as performance improvement and reimbursement;
- On-site TA visits are made to provide assistance in areas such as recruitment programs, leadership development initiatives, and EMS issues; and
- Assistance is provided for the development and implementation of mini-grant projects.

2. Assistance - Permanent Program

The Rural Hospital Flexibility Program is a permanent program under Medicare. Facilities which have converted or may plan to convert to CAH status need to be aware of policies and procedures which govern the program. Most notably, these include assistance in the interpretation of federal and state laws and regulations pertaining to CAH designation and certification procedures (see APPENDIX C). Other areas may include reimbursement and state licensure.

The Office of Rural Health functions as a point of contact for facilities. If the Office can't answer a question or provide assistance, the Office will locate an appropriate individual/entity.

3. Assistance - Grant Program

It is expected that federal grant funds administered by the Federal Office of Rural Health Policy will be used to implement the Rural Hospital Flexibility Program. Grant program goals areas have been developed for six areas. These include:

- State Rural Health Plan Development - the Plan must be sent to CMS and should outline the scope of the Rural Hospital Flexibility Program in each state.
- CAH Designation - grant funds may be used to assist communities in undertaking assessments to ascertain feasibility of conversion to CAH status. Ultimately this will result in state designation and certification by Medicare.
- Rural Network Development - all designated CAHs must be a member of a rural health network. One member of the network must be a referral hospital. Other network members are at the discretion of the CAH and may include emergency medical care providers (e.g. ambulance services); other hospitals; and other entities having written agreements with the CAH for the purpose of providing or enhancing health services within the community or service area. Grant funds may be used to develop or enhance such networking activities. In South Dakota, emphasis is placed on activities that enhance patient care using telecommunications/telemedicine linkages; Healthy People 2010 projects; and related.
- Emergency Medical Services - grant funds may be used to strengthen the provision of emergency medical care, especially in rural areas where such services are essential. Emphasis will be placed on projects that strengthen the integration of emergency medical care with the existing health care system and trauma services.
- Quality of Care and Performance Improvement - projects that either attempt to measure quality of care or improve quality of care within the CAH setting may be supported by grant funds. The Office of Rural Health is interested primarily in leadership development and working with the QIO to improve clinical quality the next few years.
- Evaluation - some grant funds will be used to collect information and measure the degree of success of the program. One method to complete this process is through participation in the multi-state benchmarking project.

H. PROCEDURE FOR PLAN REVIEW AND REVISION

The South Dakota Department of Health has authority under Public Law 105-33 for administration of the South Dakota Critical Access Hospital Program. South Dakota Office of Rural Health staff will monitor changes in federal and state laws, rules and policies that apply to the CAH program. New editions of the Plan will be developed as these changes occur. The new editions will be provided to CMS and the SoDaCAHP Steering Committee for review and comment. After they are completed, the most current edition of the Plan will be published on the Office of Rural Health web site at www.ruralhealth.sd.gov .

Changes in state regulations, as prompted by revisions in the Plan, or for any other reason, will follow the normal process of public notice as set forth in administrative procedures.

APPENDIX A

Application for Designation Form

APPLICATION FOR DESIGNATION AS A
CRITICAL ACCESS HOSPITAL
(SOUTH DAKOTA CRITICAL ACCESS HOSPITAL PROGRAM)

I, _____, Administrator (or other officer of the hospital having the authority to bind the facility), certify that

(Name and Address of Applicant)
_____
_____
_____
_____

currently meets the following criteria:

A. Please Check the Appropriate Statements and Complete Required Sections

Criterion 1: Eligibility

_____ Is a nonprofit or public hospital and is located in either: 1) a county (or equivalent unit of local government) in a rural area as defined in section 1886(d)(2)(D) of the Social Security Act; or 2) any municipality of under 3,500 which is situated in a MSA but is more than 15 miles from a city of at least 50,000 population.

Criterion 2: Location relative to other facilities or necessary provider certification

_____ The CAH is located more than a 35-mile drive from a hospital or another CAH; or

_____ In the case of mountainous terrain or in areas with only secondary roads available, the CAH is located more than a 15-mile drive from a hospital or another CAH.

Note: Per the Code of Federal Regulations (42CFR485.610), effective January 1, 2006, the State of South Dakota cannot designate new CAHs using the necessary provider criteria.

Criterion 3: Member of a rural health network

(Please submit copies of agreements with application)

_____ Has signed written agreements with at least one Referral Hospital that is a member of the network pertaining to: 1) emergency and non-emergency patient referral and transfer; 2) the development and use of communications systems (if the network has in operation such a system); and 3) the provision of emergency and non-emergency transportation.
The Referral Hospital must demonstrate sufficient resources which include: at least three full time physicians on staff; demonstrated history of accepting patient referrals/transfers from the Applicant; and licensure as a general hospital.

Referral Hospital: _____
(Facility Name)

Address: _____
_____
_____
_____

_____ Has a signed written agreement describing the process for credentialing and quality assurance with at least one hospital that is a member of the network or with the South Dakota Foundation for Medical Care (QIO).

_____
(Facility or Entity Name)

Address: _____
_____
_____
_____

Criterion 4: Emergency services

_____ Makes available 24-hour emergency care services, seven days week, regardless of inpatient census (at least one physician on duty or on call at all times and available to the hospital on-site or by telephone within 20 minutes).

Criterion 5: Bed size

_____ Agrees to provide no more than 25 licensed beds.

_____ Agrees to provide no more than 15 swing beds.

Criterion 6: Staffing

_____ Agrees to maintain staffing levels of at least one registered nurse if the facility has at least one acute care patient, or one licensed nurse if the facility has no acute care patients.

Criterion 7: Acute care inpatient length of stay

_____ Agrees to or has a written policy in effect for providing inpatient care for a period that does not exceed, as determined on an annual, average basis, 96 hours per patient.

B. Supporting Documentation

Criterion 3: Member of a rural health network

Please indicate the number of Referral Hospital medical staff for each specialty listed.

Active Medical Staff

_____ Family Practice Physician
_____ General Internal Medicine
_____ General Surgeon
_____ OB/GYN
_____ Orthopod
_____ Radiologist

Emergency Room Staffing

_____ Physicians (on-site)
_____ Physicians (on-call)
_____ Other (Please specify)_____

Courtesy/Consulting Staff

_____	Pathologist	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____
_____	_____	_____	_____

Please complete the following.

_____ Number of referrals/transfers from the Applicant to the Referral Hospital in last fiscal year

_____ Referral Hospital market share of the county in which Applicant is located

Please complete the following pertaining to the Applicant.

_____ Number of licensed acute care beds (current)
_____ Number of swing-beds (current)
_____ Number of licensed beds (CAH) – may not exceed 25 beds
_____ Number of swing beds (CAH)

Activity	Completed (Date)	Planned (Date)	Not Planned
Financial feasibility study for CAH			
Medical Staff Planning/ Education			
Hospital Board Planning/Education			
Community Planning/ Education			

_____

Signature

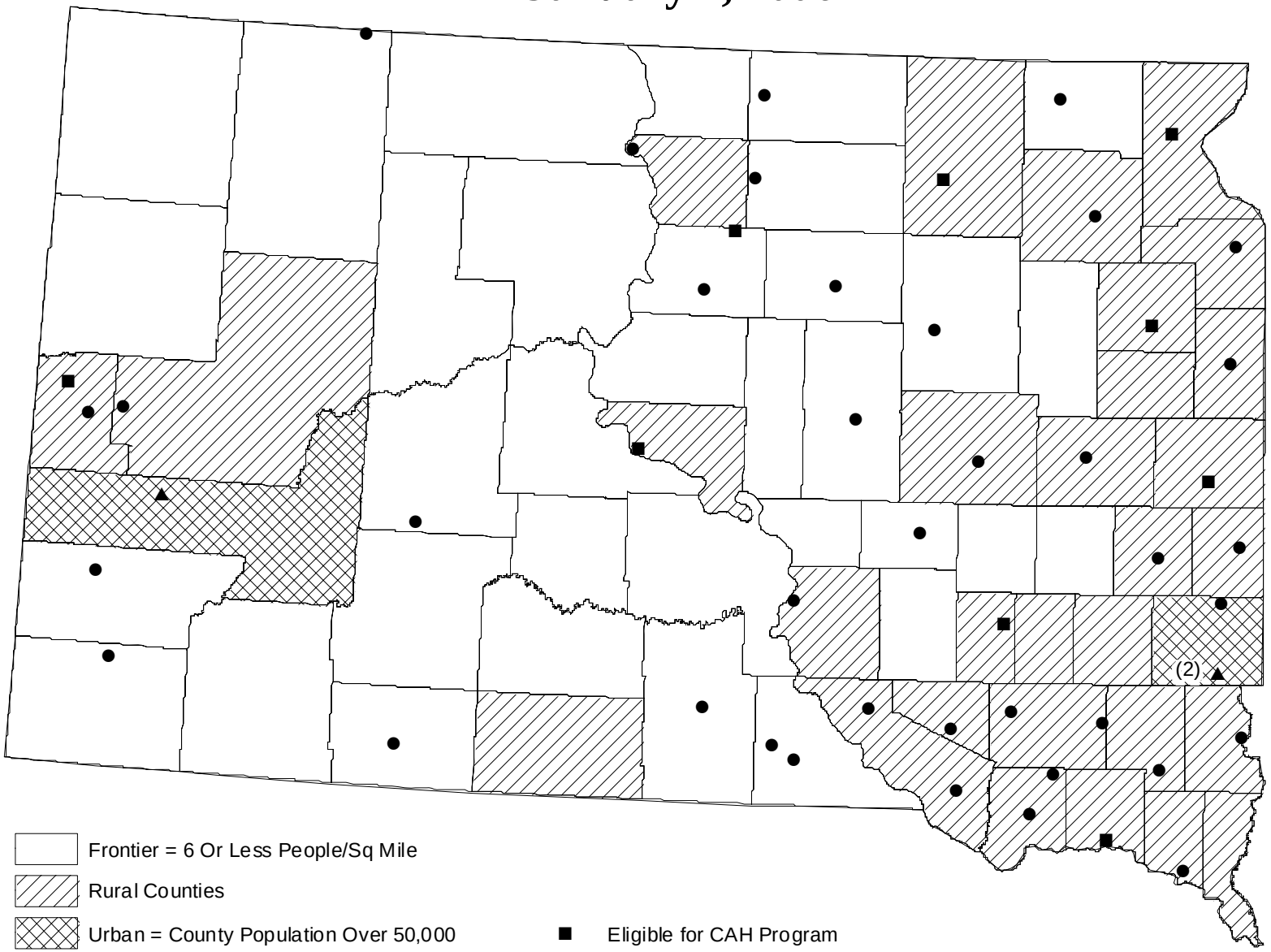
_____

Date

APPENDIX B

MAP
South Dakota Community Hospitals

South Dakota Community Hospitals
January 1, 2006



Definitions for CAH status are on pp 8-9

APPENDIX C

Applicable Federal and State Program Laws and Regulations

[Code of Federal Regulations]
[Title 42, Volume 3]
[Revised as of October 1, 2005]
From the U.S. Government Printing Office via GPO Access
[CITE: 42CFR485.601-647]

[Pages 601-614]

TITLE 42--PUBLIC HEALTH

CHAPTER IV--CENTERS FOR MEDICARE & MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES (CONTINUED)

PART 485_CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS—Table of Contents

Subpart F_Conditions of Participation: Critical Access Hospitals (CAHs)

Sec. 485.601 Basis and scope.

Source: 58 FR 30671, May 26, 1993, unless otherwise noted.

(a) Statutory basis. This subpart is based on section 1820 of the Act which sets forth the conditions for designating certain hospitals as CAHs.

(b) Scope. This subpart sets forth the conditions that a hospital must meet to be designated as a CAH.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

Sec. 485.602 Definitions.

As used in this subpart, unless the context indicates otherwise:

Direct services means services provided by employed staff of the CAH, not services provided through arrangements or agreements.

[59 FR 45403, Sept. 1, 1994, as amended at 62 FR 46037, Aug. 29, 1997]

Sec. 485.603 Rural health network.

A rural health network is an organization that meets the following specifications:

(a) It includes--

(1) At least one hospital that the State has designated or plans to designate as a CAH; and

(2) At least one hospital that furnishes acute care services.

(b) The members of the organization have entered into agreements regarding--

(1) Patient referral and transfer;

(2) The development and use of communications systems, including, where feasible, telemetry systems and systems for electronic sharing of patient data; and

(3) The provision of emergency and nonemergency transportation among members.

(c) Each CAH has an agreement with respect to credentialing and quality assurance with at least--

(1) One hospital that is a member of the network when applicable;

(2) One QIO or equivalent entity; or

(3) One other appropriate and qualified entity identified in the State rural health care plan.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46035, Aug. 29, 1997; 63 FR 26359, May 12, 1998]

Sec. 485.604 Personnel qualifications.

Staff that furnish services in a CAH must meet the applicable requirements of this section.

(a) Clinical nurse specialist. A clinical nurse specialist must be a person who performs the services of a clinical nurse specialist as authorized by the State, in accordance with State law or the State regulatory mechanism provided by State law.

(b) Nurse practitioner. A nurse practitioner must be a registered professional nurse who is currently licensed to practice in the State, who meets the State's requirements governing the qualification of nurse practitioners, and who meets one of the following conditions:

(1) Is currently certified as a primary care nurse practitioner by the American Nurses' Association or by the National Board of Pediatric Nurse Practitioners and Associates.

(2) Has successfully completed a 1 academic year program that--

(i) Prepares registered nurses to perform an expanded role in the delivery of primary care;

(ii) Includes at least 4 months (in the aggregate) of classroom instruction and a component of supervised clinical practice; and

(iii) Awards a degree, diploma, or certificate to persons who successfully complete the program.

(3) Has successfully completed a formal educational program (for preparing registered nurses to perform an expanded role in the delivery of primary care) that does not meet the requirements of paragraph (a)(2) of this section, and has been performing an expanded role in the delivery of primary care for a total of 12 months during the 18-month period immediately preceding June 25, 1993.

(c) Physician assistant. A physician assistant must be a person who meets the applicable State requirements governing the qualifications for assistants to primary care physicians, and who meets at least one of the following conditions:

(1) Is currently certified by the National Commission on Certification of Physician Assistants to assist primary care physicians.

(2) Has satisfactorily completed a program for preparing physician assistants that--

(i) Was at least one academic year in length;

(ii) Consisted of supervised clinical practice and at least 4 months (in the aggregate) of classroom instruction directed toward preparing students to deliver health care; and

(iii) Was accredited by the American Medical Association's Committee on Allied Health Education and Accreditation.

(3) Has satisfactorily completed a formal educational program (for preparing physician assistants) that does not meet the requirements of paragraph (c)(2) of this section and has been assisting primary care physicians for a total of 12 months during the 18-month period immediately preceding June 25, 1993.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

Sec. 485.606 Designation and certification of CAHs.

(a) Criteria for State designation. (1) A State that has established a Medicare rural hospital flexibility program described in section 1820(c) of the Act may designate one or more facilities as CAHs if each facility meets the CAH conditions of participation in this subpart F.

(2) The State must not deny any hospital that is otherwise eligible for designation as a CAH under this paragraph (a) solely because the hospital has entered into an agreement under which the hospital may

provide posthospital SNF care as described in Sec. 482.66 of this chapter.

(b) Criteria for CMS certification. CMS certifies a facility as a CAH if--

(1) The facility is designated as a CAH by the State in which it is located and has been surveyed by the State survey agency or by CMS and found to meet all conditions of participation in this Part and all other applicable requirements for participation in Part 489 of this chapter.

(2) The facility is a medical assistance facility operating in Montana or a rural primary care hospital designated by CMS before August 5, 1997, and is otherwise eligible to be designated as a CAH by the State under the rules in this subpart.

[62 FR 46036, Aug. 29, 1997, as amended at 63 FR 26359, May 12, 1998]

Sec. 485.608 Condition of participation: Compliance with Federal, State, and local laws and regulations.

The CAH and its staff are in compliance with applicable Federal, State and local laws and regulations.

(a) Standard: Compliance with Federal laws and regulations. The CAH is in compliance with applicable Federal laws and regulations related to the health and safety of patients.

(b) Standard: Compliance with State and local laws and regulations. All patient care services are furnished in accordance with applicable State and local laws and regulations.

(c) Standard: Licensure of CAH. The CAH is licensed in accordance with applicable Federal, State and local laws and regulations.

(d) Standard: Licensure, certification or registration of personnel. Staff of the CAH are licensed, certified, or registered in accordance with applicable Federal, State, and local laws and regulations.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

Sec. 485.610 Condition of participation: Status and location.

(a) Standard: Status. The facility is--

(1) A currently participating hospital that meets all conditions of participation set forth in this subpart;

(2) A recently closed facility, provided that the facility--

(i) Was a hospital that ceased operations on or after the date that is 10 years before November 29, 1999; and

(ii) Meets the criteria for designation under this subpart as of the effective date of its designation; or

(3) A health clinic or a health center (as defined by the State) that--

(i) Is licensed by the State as a health clinic or a health center;

(ii) Was a hospital that was downsized to a health clinic or a health center; and

(iii) As of the effective date of its designation, meets the criteria for designation set forth in this subpart.

(b) Standard: Location in a rural area or treatment as rural. The CAH meets the requirements of either paragraph (b)(1) or (b)(2) or (b)(3) of this section.

(1) The CAH meets the following requirements:

(i) The CAH is located outside any area that is a Metropolitan Statistical Area, as defined by the Office of Management and Budget, or that has been recognized as urban under Sec. 412.64(b), excluding paragraph (b)(3) of this chapter;

(ii) The CAH has not been classified as an urban hospital for purposes of the standardized payment amount by CMS or the Medicare Geographic Classification Review Board under Sec. 412.230(e) of this

chapter, and is not among a group of hospitals that have been redesignated to an adjacent urban area under Sec. 412.232 of this chapter.

(2) The CAH is located within a Metropolitan Statistical Area, as defined by the Office of Management and Budget, but is being treated as being located in a rural area in accordance with Sec. 412.103 of this chapter.

(3) Effective only for October 1, 2004 through September 30, 2006, the CAH does not meet the location requirements in either paragraph (b)(1) or (b)(2) of this section and is located in a county that, in FY 2004, was not part of a Metropolitan Statistical Area as defined by the Office of Management and Budget, but as of FY 2005 was included as part of such an MSA as a result of the most recent census data and implementation of the new MSA definitions announced by OMB on June 6, 2003.

(c) Standard: Location relative to other facilities or necessary provider certification. The CAH is located more than a 35-mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital or another CAH, or before January 1, 2006, the CAH is certified by the State as being a necessary provider of health care services to residents in the area. A CAH that is designated as a necessary provider as of October 1, 2006, will maintain its necessary provider designation after January 1, 2006.

(d) Standard: Relocation of CAHs with a necessary provider designation. A CAH that has a necessary provider designation from the State that was in effect prior to January 1, 2006, and relocates its facility after January 1, 2006, can continue to meet the location requirement of paragraph (c) of this section based on the necessary provider designation only if the relocated facility meets the requirements as specified in paragraph (d)(1) of this section.

(1) If a necessary provider CAH relocates its facility and begins providing services in a new location, the CAH can continue to meet the location requirement of paragraph (c) of this section based on the necessary provider designation only if the CAH in its new location--

(i) Serves at least 75 percent of the same service area that it served prior to its relocation;

(ii) Provides at least 75 percent of the same services that it provided prior to the relocation; and

(iii) Is staffed by 75 percent of the same staff (including medical staff, contracted staff, and employees) that were on staff at the original location.

(2) If a CAH that has been designated as a necessary provider by the State begins providing services at another location after January 1, 2006, and does not meet the requirements in paragraph (d)(1) of this section, the action will be considered a cessation of business as described in Sec. 489.52(b)(3).

[62 FR 46036, Aug. 29, 1997, as amended at 65 FR 47052, Aug. 1, 2000; 66 FR 39938, Aug. 1, 2001; 69 FR 49271, Aug. 11, 2004; 69 FR 60252, Oct. 7, 2004; 70 FR 47490, Aug. 12, 2005]

Sec. 485.612 Condition of participation: Compliance with hospital requirements at the time of application.

Except for recently closed facilities as described in Sec. 485.610(a)(2), or health clinics or health centers as described in Sec. 485.610(a)(3), the facility is a hospital that has a provider agreement to participate in the Medicare program as a hospital at the time the hospital applies for designation as a CAH.

[66 FR 32196, June 13, 2001]

Sec. 485.616 Condition of participation: Agreements.

(a) Standard: Agreements with network hospitals. In the case of a CAH that is a member of a rural health network as defined in Sec. 485.603 of this chapter, the CAH has in effect an agreement with at least one hospital that is a member of the network for--

(1) Patient referral and transfer;

(2) The development and use of communications systems of the network, including the network's system for the electronic sharing of patient data, and telemetry and medical records, if the network has in operation such a system; and

(3) The provision of emergency and nonemergency transportation between the facility and the hospital.

(b) Standard: Agreements for credentialing and quality assurance. Each CAH that is a member of a rural health network shall have an agreement with respect to credentialing and quality assurance with at least--

(1) One hospital that is a member of the network;

(2) One QIO or equivalent entity; or

(3) One other appropriate and qualified entity identified in the State rural health care plan.

[62 FR 46036, Aug. 29, 1997]

Sec. 485.618 Condition of participation: Emergency services.

The CAH provides emergency care necessary to meet the needs of its inpatients and outpatients.

(a) Standard: Availability. Emergency services are available on a 24-hours a day basis.

(b) Standard: Equipment, supplies, and medication. Equipment, supplies, and medication used in treating emergency cases are kept at the CAH and are readily available for treating emergency cases. The items available must include the following:

(1) Drugs and biologicals commonly used in life-saving procedures, including analgesics, local anesthetics, antibiotics, anticonvulsants, antidotes and emetics, serums and toxoids, antiarrythmics, cardiac glycosides, antihypertensives, diuretics, and electrolytes and replacement solutions.

(2) Equipment and supplies commonly used in life-saving procedures, including airways, endotracheal tubes, ambu bag/valve/mask, oxygen, tourniquets, immobilization devices, nasogastric tubes, splints, IV therapy supplies, suction machine, defibrillator, cardiac monitor, chest tubes, and indwelling urinary catheters.

(c) Standard: Blood and blood products. The facility provides, either directly or under arrangements, the following:

(1) Services for the procurement, safekeeping, and transfusion of blood, including the availability of blood products needed for emergencies on a 24-hours a day basis.

(2) Blood storage facilities that meet the requirements of 42 CFR part 493, subpart K, and are under the control and supervision of a pathologist or other qualified doctor of medicine or osteopathy. If blood banking services are provided under an arrangement, the arrangement is approved by the facility's medical staff and by the persons directly responsible for the operation of the facility.

(d) Standard: Personnel. (1) Except as specified in paragraph (d)(2) of this section, there must be a doctor of medicine or osteopathy, a physician assistant, a nurse practitioner, or a clinical nurse specialist, with training or experience in emergency care on call and immediately available by telephone or radio contact, and available onsite within the following timeframes:

(i) Within 30 minutes, on a 24-hour a day basis, if the CAH is

located in an area other than an area described in paragraph (d)(1)(ii) of this section; or

(ii) Within 60 minutes, on a 24-hour a day basis, if all of the following requirements are met:

(A) The CAH is located in an area designated as a frontier area (that is, an area with fewer than six residents per square mile based on the latest population data published by the Bureau of the Census) or in an area that meets the criteria for a remote location adopted by the State in its rural health care plan, and approved by CMS, under section 1820(b) of the Act.

(B) The State has determined, under criteria in its rural health care plan, that allowing an emergency response time longer than 30 minutes is the only feasible method of providing emergency care to residents of the area served by the CAH.

(C) The State maintains documentation showing that the response time of up to 60 minutes at a particular CAH it designates is justified because other available alternatives would increase the time needed to stabilize a patient in an emergency.

(2) A registered nurse satisfies the personnel requirement specified in paragraph (d)(1) of this section for a temporary period if--

(i) The CAH has no greater than 10 beds;

(ii) The CAH is located in an area designated as a frontier area or remote location as described in paragraph (d)(1)(ii)(A) of this section;

(iii) The State in which the CAH is located submits a letter to CMS signed by the Governor, following consultation on the issue of using RNs on a temporary basis as part of their State rural healthcare plan with the State Boards of Medicine and Nursing, and in accordance with State law, requesting that a registered nurse with training and experience in emergency care be included in the list of personnel specified in paragraph (d)(1) of this section. The letter from the Governor must attest that he or she has consulted with State Boards of Medicine and Nursing about issues related to access to and the quality of emergency services in the States. The letter from the Governor must also describe the circumstances and duration of the temporary request to include the registered nurses on the list of personnel specified in paragraph (d)(1) of this section;

(iv) Once a Governor submits a letter, as specified in paragraph (d)(2)(iii) of this section, a CAH must submit documentation to the State survey agency demonstrating that it has been unable, due to the shortage of such personnel in the area, to provide adequate coverage as specified in this paragraph (d).

(3) The request, as specified in paragraph(d)(2)(iii) of this section, and the withdrawal of the request, may be submitted to us at any time, and are effective upon submission.

(e) Standard: Coordination with emergency response systems. The CAH must, in coordination with emergency response systems in the area, establish procedures under which a doctor of medicine or osteopathy is immediately available by telephone or radio contact on a 24-hours a day basis to receive emergency calls, provide information on treatment of emergency patients, and refer patients to the CAH or other appropriate locations for treatment.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997; 64 FR 41544, July 30, 1999; 67 FR 80041, Dec. 31, 2002; 69 FR 49271, Aug. 11, 2004]

Sec. 485.620 Condition of participation: Number of beds and length of stay.

(a) Standard: Number of beds. Except as permitted for CAHs having distinct part units under Sec. 485.647, the CAH maintains no more than 25 inpatient beds after January 1, 2004, that can be used for either inpatient or swing-bed services.

(b) Standard: Length of stay. The CAH provides acute inpatient care for a period that does not exceed, on an annual average basis, 96 hours per patient.

[62 FR 46036, Aug. 29, 1997, as amended at 65 FR 47052, Aug. 1, 2000; 69 FR 49271, Aug. 11, 2004; 69 FR 60252, Oct. 7, 2004]

Sec. 485.623 Condition of participation: Physical plant and environment.

(a) Standard: Construction. The CAH is constructed, arranged, and maintained to ensure access to and safety of patients, and provides adequate space for the provision of direct services.

(b) Standard: Maintenance. The CAH has housekeeping and preventive maintenance programs to ensure that--

(1) All essential mechanical, electrical, and patient-care equipment is maintained in safe operating condition;

(2) There is proper routine storage and prompt disposal of trash;

(3) Drugs and biologicals are appropriately stored;

(4) The premises are clean and orderly; and

(5) There is proper ventilation, lighting, and temperature control in all pharmaceutical, patient care, and food preparation areas.

(c) Standard: Emergency procedures. The CAH assures the safety of patients in non-medical emergencies by--

(1) Training staff in handling emergencies, including prompt reporting of fires, extinguishing of fires, protection and, where necessary, evacuation of patients, personnel, and guests, and cooperation with fire fighting and disaster authorities;

(2) Providing for emergency power and lighting in the emergency room and for battery lamps and flashlights in other areas;

(3) Providing for an emergency fuel and water supply; and

(4) Taking other appropriate measures that are consistent with the particular conditions of the area in which the CAH is located.

(d) Standard: Life safety from fire. (1) Except as otherwise provided in this section--

(i) The CAH must meet the applicable provisions of the 2000 edition of the Life Safety Code of the National Fire Protection Association. The Director of the Office of the Federal Register has approved the NFPA 101[reg] 2000 edition of the Life Safety Code, issued January 14, 2000, for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the Code is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD or at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: http://www.archives.gov/federal--register/code--of--federal--regulations/ibr--locations.html. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any changes in this edition of the Code are incorporated by reference, CMS will publish notice in the Federal Register to announce the changes.

(ii) Chapter 19.3.6.3.2, exception number 2 of the adopted edition of the Life Safety Code does not apply to a CAH.

(2) If CMS finds that the State has a fire and safety code imposed by State law that adequately protects patients, CMS may allow the State survey agency to apply the State's fire and safety code instead of the LSC.

(3) After consideration of State survey agency findings, CMS may waive specific provisions of the Life Safety Code that, if rigidly applied, would result in unreasonable hardship on the CAH, but only if the waiver does not adversely affect the health and safety of patients.

(4) The CAH maintains written evidence of regular inspection and approval by State or local fire control agencies.

(5) Beginning March 13, 2006, a critical access hospital must be in

compliance with Chapter 9.2.9, Emergency Lighting.

(6) Beginning March 13, 2006, Chapter 19.3.6.3.2, exception number 2 does not apply to critical access hospitals.

(7) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a critical access hospital may install alcohol-based hand rub dispensers in its facility if--

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00-1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00-1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this amendment, CMS will publish notice in the Federal Register to announce the change.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46036, 46037, Aug. 29, 1997; 68 FR 1387, Jan. 10, 2003; 69 FR 49271, Aug. 11, 2004; 70 FR 15239, Mar. 25, 2005]

Sec. 485.627 Condition of participation: Organizational structure.

(a) Standard: Governing body or responsible individual. The CAH has a governing body or an individual that assumes full legal responsibility for determining, implementing and monitoring policies governing the CAH's total operation and for ensuring that those policies are administered so as to provide quality health care in a safe environment.

(b) Standard: Disclosure. The CAH discloses the names and addresses of--

(1) Its owners, or those with a controlling interest in the CAH or in any subcontractor in which the CAH directly or indirectly has a 5 percent or more ownership interest, in accordance with subpart C of part 420 of this chapter;

(2) The person principally responsible for the operation of the CAH; and

(3) The person responsible for medical direction.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

Sec. 485.631 Condition of participation: Staffing and staff responsibilities.

(a) Standard: Staffing--(1) The CAH has a professional health care staff that includes one or more doctors of medicine or osteopathy, and may include one or more physician assistants, nurse practitioners, or clinical nurse specialists.

(2) Any ancillary personnel are supervised by the professional staff.

(3) The staff is sufficient to provide the services essential to the operation of the CAH.

(4) A doctor of medicine or osteopathy, nurse practitioner, clinical nurse specialist, or physician assistant is available to furnish patient care services at all times the CAH operates.

(5) A registered nurse, clinical nurse specialist, or licensed practical nurse is on duty whenever the CAH has one or more inpatients.

(b) Standard: Responsibilities of the doctor of medicine or osteopathy. (1) The doctor of medicine or osteopathy--

(i) Provides medical direction for the CAH's health care activities and consultation for, and medical supervision of, the health care staff;

(ii) In conjunction with the physician assistant and/or nurse practitioner member(s), participates in developing, executing, and periodically reviewing the CAH's written policies governing the services it furnishes.

(iii) In conjunction with the physician assistant and/or nurse practitioner members, periodically reviews the CAH's patient records, provides medical orders, and provides medical care services to the patients of the CAH; and

(iv) Periodically reviews and signs the records of patients cared for by nurse practitioners, clinical nurse specialists, or physician assistants.

(2) A doctor of medicine or osteopathy is present for sufficient periods of time, at least once in every 2 week period (except in extraordinary circumstances) to provide the medical direction, medical care services, consultation, and supervision described in this paragraph, and is available through direct radio or telephone communication for consultation, assistance with medical emergencies, or patient referral. The extraordinary circumstances are documented in the records of the CAH. A site visit is not required if no patients have been treated since the latest site visit.

(c) Standard: Physician assistant, nurse practitioner, and clinical nurse specialist responsibilities. (1) The physician assistant, the nurse practitioner, or clinical nurse specialist members of the CAH's staff--

(i) Participate in the development, execution and periodic review of the written policies governing the services the CAH furnishes; and

(ii) Participate with a doctor of medicine or osteopathy in a periodic review of the patients' health records.

(2) The physician assistant, nurse practitioner, or clinical nurse specialist performs the following functions to the extent they are not being performed by a doctor of medicine or osteopathy:

(i) Provides services in accordance with the CAH's policies.

(ii) Arranges for, or refers patients to, needed services that cannot be furnished at the CAH, and assures that adequate patient health records are maintained and transferred as required when patients are referred.

(3) Whenever a patient is admitted to the CAH by a nurse practitioner, physician assistant, or clinical nurse specialist, a doctor of medicine or osteopathy on the staff of the CAH is notified of the admission.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

Sec. 485.635 Condition of participation: Provision of services.

(a) Standard: Patient care policies. (1) The CAH's health care services are furnished in accordance with appropriate written policies that are consistent with applicable State law.

(2) The policies are developed with the advice of a group of professional personnel that includes one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff under the provisions of Sec. 485.631(a)(1); at least one member is not a member of the CAH

staff.

(3) The policies include the following: (i) A description of the services the CAH furnishes directly and those furnished through agreement or arrangement.

(ii) Policies and procedures for emergency medical services.

(iii) Guidelines for the medical management of health problems that include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the CAH.

(iv) Rules for the storage, handling, dispensation, and administration of drugs and biologicals. These rules must provide that there is a drug storage area that is administered in accordance with accepted professional principles, that current and accurate records are kept of the receipt and disposition of all scheduled drugs, and that outdated, mislabeled, or otherwise unusable drugs are not available for patient use.

(v) Procedures for reporting adverse drug reactions and errors in the administration of drugs.

(vi) A system for identifying, reporting, investigating and controlling infections and communicable diseases of patients and personnel.

(vii) If the CAH furnishes inpatient services, procedures that ensure that the nutritional needs of inpatients are met in accordance with recognized dietary practices and the orders of the practitioner responsible for the care of the patients, and that the requirement of Sec. 483.25(i) is met with respect to inpatients receiving posthospital SNF care.

(4) These policies are reviewed at least annually by the group of professional personnel required under paragraph (a)(2) of this section, and reviewed as necessary by the CAH.

(b) Standard: Direct services--(1) General. The CAH staff furnishes, as direct services, those diagnostic and therapeutic services and supplies that are commonly furnished in a physician's office or at another entry point into the health care delivery system, such as a low intensity hospital outpatient department or emergency department. These direct services include medical history, physical examination, specimen collection, assessment of health status, and treatment for a variety of medical conditions.

(2) Laboratory services. The CAH provides, as direct services, basic laboratory services essential to the immediate diagnosis and treatment of the patient that meet the standards imposed under section 353 of the Public Health Service Act (42 U.S.C. 236a). (See the laboratory requirements specified in part 493 of this chapter.) The services provided include:

(i) Chemical examination of urine by stick or tablet method or both (including urine ketones);

(ii) Hemoglobin or hematocrit;

(iii) Blood glucose:

(iv) Examination of stool specimens for occult blood;

(v) Pregnancy tests; and

(vi) Primary culturing for transmittal to a certified laboratory.

(3) Radiology services. Radiology services furnished at the CAH are provided as direct services by staff qualified under State law, and do not expose CAH patients or staff to radiation hazards.

(4) Emergency procedures. In accordance with the requirements of Sec. 485.618, the CAH provides as direct services medical emergency procedures as a first response to common life-threatening injuries and acute illness.

(c) Standard: Services provided through agreements or arrangements. (1) The CAH has agreements or arrangements (as appropriate) with one or more providers or suppliers participating under Medicare to furnish other services to its patients, including--

(i) Inpatient hospital care;

(ii) Services of doctors of medicine or osteopathy; and
(iii) Additional or specialized diagnostic and clinical laboratory services that are not available at the CAH.
(iv) Food and other services to meet inpatients' nutritional needs to the extent these services are not provided directly by the CAH.
(2) If the agreements or arrangements are not in writing, the CAH is able to present evidence that patients referred by the CAH are being accepted and treated.
(3) The CAH maintains a list of all services furnished under arrangements or agreements. The list describes the nature and scope of the services provided.
(4) The person principally responsible for the operation of the CAH under Sec. 485.627(b)(2) of this chapter is also responsible for the following:
(i) Services furnished in the CAH whether or not they are furnished under arrangements or agreements.
(ii) Ensuring that a contractor of services (including one for shared services and joint ventures) furnishes services that enable the CAH to comply with all applicable conditions of participation and standards for the contracted services.
(d) Standard: Nursing services. Nursing services must meet the needs of patients.
(1) A registered nurse must provide (or assign to other personnel) the nursing care of each patient, including patients at a SNF level of care in a swing-bed CAH. The care must be provided in accordance with the patient's needs and the specialized qualifications and competence of the staff available.
(2) A registered nurse or, where permitted by State law, a physician assistant, must supervise and evaluate the nursing care for each patient, including patients at a SNF level of care in a swing-bed CAH.
(3) All drugs, biologicals, and intravenous medications must be administered by or under the supervision of a registered nurse, a doctor of medicine or osteopathy, or, where permitted by State law, a physician assistant, in accordance with written and signed orders, accepted standards of practice, and Federal and State laws.
(4) A nursing care plan must be developed and kept current for each inpatient.

[58 FR 30671, May 26, 1993; 58 FR 49935, Sept. 24, 1993, as amended at 59 FR 45403, Sept. 1, 1994; 62 FR 46037, Aug. 29, 1997]

Sec. 485.638 Conditions of participation: Clinical records.

(a) Standard: Records system.--(1) The CAH maintains a clinical records system in accordance with written policies and procedures.
(2) The records are legible, complete, accurately documented, readily accessible, and systematically organized.
(3) A designated member of the professional staff is responsible for maintaining the records and for ensuring that they are completely and accurately documented, readily accessible, and systematically organized.
(4) For each patient receiving health care services, the CAH maintains a record that includes, as applicable--
(i) Identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;
(ii) Reports of physical examinations, diagnostic and laboratory test results, including clinical laboratory services, and consultative findings;
(iii) All orders of doctors of medicine or osteopathy or other practitioners, reports of treatments and medications, nursing notes and documentation of complications, and other pertinent information

necessary to monitor the patient's progress, such as temperature graphics, progress notes describing the patient's response to treatment; and

(iv) Dated signatures of the doctor of medicine or osteopathy or other health care professional.

(b) Standard: Protection of record information--(1) The CAH maintains the confidentiality of record information and provides safeguards against loss, destruction, or unauthorized use.

(2) Written policies and procedures govern the use and removal of records from the CAH and the conditions for the release of information.

(3) The patient's written consent is required for release of information not required by law.

(c) Standard: Retention of records. The records are retained for at least 6 years from date of last entry, and longer if required by State statute, or if the records may be needed in any pending proceeding.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997]

Sec. 485.639 Condition of participation: Surgical services.

Surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body of the CAH in accordance with the designation requirements under paragraph (a) of this section.

(a) Designation of qualified practitioners. The CAH designates the practitioners who are allowed to perform surgery for CAH patients, in accordance with its approved policies and procedures, and with State scope of practice laws. Surgery is performed only by--

(1) A doctor of medicine or osteopathy, including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(2) A doctor of dental surgery or dental medicine; or

(3) A doctor of podiatric medicine.

(b) Anesthetic risk and evaluation. (1) A qualified practitioner, as specified in paragraph (a) of this section, must examine the patient immediately before surgery to evaluate the risk of the procedure to be performed.

(2) A qualified practitioner, as specified in paragraph (c) of this section, must examine each patient before surgery to evaluate the risk of anesthesia.

(3) Before discharge from the CAH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner, as specified in paragraph (c) of this section.

(c) Administration of anesthesia. The CAH designates the person who is allowed to administer anesthesia to CAH patients in accordance with its approved policies and procedures and with State scope-of-practice laws.

(1) Anesthesia must be administered by only--

(i) A qualified anesthesiologist;

(ii) A doctor of medicine or osteopathy other than an anesthesiologist; including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(iii) A doctor of dental surgery or dental medicine;

(iv) A doctor of podiatric medicine;

(v) A certified registered nurse anesthetist (CRNA), as defined in Sec. 410.69(b) of this chapter;

(vi) An anesthesiologist's assistant, as defined in Sec. 410.69(b) of this chapter; or

(vii) A supervised trainee in an approved educational program, as described in Sec. Sec. 413.85 or 413.86 of this chapter.

(2) In those cases in which a CRNA administers the anesthesia, the anesthetist must be under the supervision of the operating practitioner except as provided in paragraph (e) of this section. An

anesthesiologist's assistant who administers anesthesia must be under the supervision of an anesthesiologist.

(d) Discharge. All patients are discharged in the company of a responsible adult, except those exempted by the practitioner who performed the surgical procedure.

(e) Standard: State exemption. (1) A CAH may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (c)(2) of this section, if the State in which the CAH is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision for CRNAs. The letter from the Governor must attest that he or she has consulted with the State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the State and has concluded that it is in the best interests of the State's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with State law.

(2) The request for exemption and recognition of State laws and the withdrawal of the request may be submitted at any time, and are effective upon submission.

[60 FR 45851, Sept. 1, 1995, as amended at 62 FR 46037, Aug. 29, 1997; 66 FR 39938, Aug. 1, 2001; 66 FR 56769, Nov. 13, 2001]

Sec. 485.641 Condition of participation: Periodic evaluation and quality assurance review.

(a) Standard: Periodic evaluation--(1) The CAH carries out or arranges for a periodic evaluation of its total program. The evaluation is done at least once a year and includes review of--

(i) The utilization of CAH services, including at least the number of patients served and the volume of services;

(ii) A representative sample of both active and closed clinical records; and

(iii) The CAH's health care policies.

(2) The purpose of the evaluation is to determine whether the utilization of services was appropriate, the established policies were followed, and any changes are needed.

(b) Standard: Quality assurance. The CAH has an effective quality assurance program to evaluate the quality and appropriateness of the diagnosis and treatment furnished in the CAH and of the treatment outcomes. The program requires that--

(1) All patient care services and other services affecting patient health and safety, are evaluated;

(2) Nosocomial infections and medication therapy are evaluated;

(3) The quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialists, and physician assistants at the CAH are evaluated by a member of the CAH staff who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the CAH;

(4) The quality and appropriateness of the diagnosis and treatment furnished by doctors of medicine or osteopathy at the CAH are evaluated by--

(i) One hospital that is a member of the network, when applicable;

(ii) One QIO or equivalent entity; or

(iii) One other appropriate and qualified entity identified in the State rural health care plan; and

(5)(i) The CAH staff considers the findings of the evaluations, including any findings or recommendations of the QIO, and takes corrective action if necessary.

(ii) The CAH also takes appropriate remedial action to address deficiencies found through the quality assurance program.

(iii) The CAH documents the outcome of all remedial action.

[58 FR 30671, May 26, 1993, as amended at 62 FR 46037, Aug. 29, 1997; 63 FR 26359, May 12, 1998]

Sec. 485.643 Condition of participation: Organ, tissue, and eye procurement.

The CAH must have and implement written protocols that:

(a) Incorporate an agreement with an OPO designated under part 486 of this chapter, under which it must notify, in a timely manner, the OPO or a third party designated by the OPO of individuals whose death is imminent or who have died in the CAH. The OPO determines medical suitability for organ donation and, in the absence of alternative arrangements by the CAH, the OPO determines medical suitability for tissue and eye donation, using the definition of potential tissue and eye donor and the notification protocol developed in consultation with the tissue and eye banks identified by the CAH for this purpose;

(b) Incorporate an agreement with at least one tissue bank and at least one eye bank to cooperate in the retrieval, processing, preservation, storage and distribution of tissues and eyes, as may be appropriate to assure that all usable tissues and eyes are obtained from potential donors, insofar as such an agreement does not interfere with organ procurement;

(c) Ensure, in collaboration with the designated OPO, that the family of each potential donor is informed of its option to either donate or not donate organs, tissues, or eyes. The individual designated by the CAH to initiate the request to the family must be a designated requestor. A designated requestor is an individual who has completed a course offered or approved by the OPO and designed in conjunction with the tissue and eye bank community in the methodology for approaching potential donor families and requesting organ or tissue donation;

(d) Encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of the families of potential donors;

(e) Ensure that the CAH works cooperatively with the designated OPO, tissue bank and eye bank in educating staff on donation issues, reviewing death records to improve identification of potential donors, and maintaining potential donors while necessary testing and placement of potential donated organs, tissues, and eyes take place.

(f) For purposes of these standards, the term ``organ'' means a human kidney, liver, heart, lung, pancreas, or intestines (or multivisceral organs).

[65 FR 47110, Aug. 1, 2000, as amended at 66 FR 39938, Aug. 1, 2001]

Sec. 485.645 Special requirements for CAH providers of long-term care services (``swing-beds'')

A CAH must meet the following requirements in order to be granted an approval from CMS to provided post-hospital SNF care, as specified in Sec. 409.30 of this chapter, and to be paid for SNF-level services, in accordance with paragraph (c) of this section.

(a) Eligibility. A CAH must meet the following eligibility requirements:

(1) The facility has been certified as a CAH by CMS under Sec. 485.606(b) of this subpart; and

(2) The facility provides not more than 25 inpatient beds. Any bed of a unit of the facility that is licensed as a distinct-part SNF at the time the facility applies to the State for designation as a CAH is not counted under paragraph (a) of this section.

(b) Facilities participating as rural primary care hospitals (RPCHs) on September 30, 1997. These facilities must meet the following

requirements:

(1) Notwithstanding paragraph (a) of this section, a CAH that participated in Medicare as a RPCH on September 30, 1997, and on that date had in effect an approval from CMS to use its inpatient facilities to provide post-hospital SNF care may continue in that status under the same terms, conditions and limitations that were applicable at the time those approvals were granted.

(2) A CAH that was granted swing-bed approval under paragraph (b)(1) of this section may request that its application to be a CAH and swing-bed provider be reevaluated under paragraph (a) of this section. If this request is approved, the approval is effective not earlier than October 1, 1997. As of the date of approval, the CAH no longer has any status under paragraph (b)(1) of this section and may not request reinstatement under paragraph (b)(1) of this section.

(c) Payment. Payment for inpatient RPCH services to a CAH that has qualified as a CAH under the provisions in paragraph (a) of this section is made in accordance with Sec. 413.70 of this chapter. Payment for post-hospital SNF-level of care services is made in accordance with the payment provisions in Sec. 413.114 of this chapter.

(d) SNF services. The CAH is substantially in compliance with the following SNF requirements contained in subpart B of part 483 of this chapter:

(1) Residents rights (Sec. 483.10(b)(3) through (b)(6), (d) (e), (h), (i), (j)(1)(vii) and (viii), (l), and (m) of this chapter).

(2) Admission, transfer, and discharge rights (Sec. 483.12(a) of this chapter).

(3) Resident behavior and facility practices (Sec. 483.13 of this chapter).

(4) Patient activities (Sec. 483.15(f) of this chapter), except that the services may be directed either by a qualified professional meeting the requirements of Sec. 485.15(f)(2), or by an individual on the facility staff who is designated as the activities director and who serves in consultation with a therapeutic recreation specialist, occupational therapist, or other professional with experience or education in recreational therapy.

(5) Social services (Sec. 483.15(g) of this chapter).

(6) Comprehensive assessment, comprehensive care plan, and discharge planning (Sec. 483.20(b), (k), and (l) of this chapter, except that the CAH is not required to use the resident assessment instrument (RAI) specified by the State that is required under Sec. 483.20(b), or to comply with the requirements for frequency, scope, and number of assessments prescribed in Sec. 413.343(b) of this chapter).

(7) Specialized rehabilitative services (Sec. 483.45 of this chapter).

(8) Dental services (Sec. 483.55 of this chapter).

(9) Nutrition (Sec. 483.25(i) of this chapter).

[63 FR 26359, May 12, 1998 as amended at 64 FR 41544, July 30, 1999; 67 FR 50120, Aug. 1, 2002; 69 FR 49272, Aug. 11, 2004]

Sec. 485.647 Condition of participation: psychiatric and rehabilitation distinct part units.

(a) Conditions.

(1) If a CAH provides inpatient psychiatric services in a distinct part unit, the services furnished by the distinct part unit must comply with the hospital requirements specified in Subparts A, B, C, and D of Part 482 of this subchapter, the common requirements of Sec. 412.25(a)(2) through (f) of Part 412 of this chapter for hospital units excluded from the prospective payment systems, and the additional requirements of Sec. 412.27 of Part 412 of this chapter for excluded psychiatric units.

(2) If a CAH provides inpatient rehabilitation services in a distinct part unit, the services furnished by the distinct part unit must comply with the hospital requirements specified in Subparts A, B, C, and D of Part 482 of this subchapter, the common requirements of Sec. 412.25(a)(2) through (f) of Part 412 of this chapter for hospital units excluded from the prospective payments systems, and the additional requirements of Sec. Sec. 412.29 and Sec. 412.30 of Part 412 of this chapter related specifically to rehabilitation units.

(b) Eligibility requirements.

(1) To be eligible to receive Medicare payments for psychiatric or rehabilitation services as a distinct part unit, the facility provides no more than 10 beds in the distinct part unit.

(2) The beds in the distinct part are excluded from the 25 inpatient-bed count limit specified in Sec. 485.620(a).

(3) The average annual 96-hour length of stay requirement specified under Sec. 485.620(b) does not apply to the 10 beds in the distinct part units specified in paragraph (b)(1) of this section, and admissions and days of inpatient care in the distinct part units are not taken into account in determining the CAH's compliance with the limits on the number of beds and length of stay in Sec. 485.620.

[69 FR 49272, Aug. 11, 2004]

SOUTH DAKOTA ADMINISTRATIVE RULE
Article 44:04

Note: The following are only excerpts from Article 44:04 that pertain to Critical Access Hospitals

44:04:01:01. Definitions. Terms defined in SDCL 34-12-1.1 have the same meaning in this article. In addition, terms used in this article mean:

(38) "Patient," a person with a valid order by a practitioner for diagnostic or treatment services in a hospital, specialized hospital, critical access hospital, swingbed, ambulatory surgery center, or chemical dependency treatment facility;

(46) "Referral hospital," a general hospital with medical personnel qualified to receive emergency and nonemergency patient transfers from a critical access hospital, which has sufficient resources to provide consultation to a critical access hospital in the areas of clinical protocols, quality assurance, utilization review, staff inservice, and business consultation;

44:04:01:02. Licensure of facilities by classification. Applications for licensure of a health care facility must set out the classification being applied for. Any license issued shall denote the classification and the facility address on the face of the license. The license shall include each facility address at which services licensed under this chapter are provided. A critical access hospital must first receive notice of eligibility for licensure from the secretary of health. A facility must comply only with those chapters in this article that apply to the classification of license issued. The most current license issued by the department must be posted on the premises of the facility in a place conspicuous to the public. Each facility address shall show a current license. The license certificate remains the property of the department. Facility classifications in addition to those defined in SDCL 34-12-1.1 are as follows:

(1) General hospital;
(2) Specialized hospital; and
(3) Hospice facility.

Source: SL 1975, ch 16, § 1; 4 SDR 14, effective September 14, 1977; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; 26 SDR 96, effective January 23, 2000; 27 SDR 59, effective December 17, 2000.
General Authority: SDCL 34-12-13.
Law Implemented: SDCL 34-12-7, 34-12-13.

44:04:01:02.01. Annual license fees for health care facilities. The annual license fees for health care facilities, which includes up to two amendment applications of the license during the licensure year, are as follows:

(1) For an ambulatory surgery center, $100;
(2) For a chemical dependency treatment facility, $100 plus $3 for each bed licensed;

(3) For a hospital, $100 plus $3 for each bed licensed, except that the fee for each bed for a hospital qualifying for exemption pursuant to SDCL 34-12-16 is $2;
(4) For a maternity home, $100 plus $3 for each bed licensed;
(5) For a nursing facility, $100 plus $3 for each bed licensed;
(6) For an assisted living center, $100 plus $3 for each bed licensed;
(7) For a critical access hospital, $100 plus $3 for each bed licensed;
(8) For a hospice facility, $100 plus $3 for each bed licensed; and
(9) For an adult foster care home, no fee.

Source: 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; 26 SDR 96, effective January 23, 2000; 30 SDR 84, effective December 4, 2003.
General Authority: SDCL 34-12-6.
Law Implemented: SDCL 34-12-6.

44:04:01:02.02. License amendment application fee. The amendment application fees for each license change in excess of two during the licensure year are as follows:

(1) For an ambulatory surgery center, $20;
(2) For a chemical dependency treatment facility, $20;
(3) For a hospital, $20;
(4) For a maternity home, $20;
(5) For a nursing facility, $20;
(6) For an assisted living center, $20;
(7) For a critical access hospital, $20;
(8) For a hospice facility, $20; and
(9) For an adult foster care home, no fee.

Source: 26 SDR 96, effective January 23, 2000.
General Authority: SDCL 34-12-6.
Law Implemented: SDCL 34-12-6.

44:04:01:04. Bed capacity. The department shall establish the bed capacity of each facility pursuant to the physical plant and space provisions of this article. The patient or resident census must not exceed the bed capacity for which the facility is licensed. A request by the facility for an adjustment in bed capacity because of change of purpose or construction must be approved by the department before any changes are made. A critical access hospital (CAH) may license no more than 25 beds. A CAH may establish a distinct part unit (e.g., psychiatric or rehabilitation) that meets requirements for such beds as established for a short-term, general hospital. Those beds may not count toward the CAH bed limit, and the total number in each distinct part unit may not exceed ten.

Source: SL 1975, ch 16, § 1; 4 SDR 14, effective September 14, 1977; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; 26 SDR 96, effective January 23, 2000; 30 SDR 84, effective December 4, 2003; 31 SDR 62, effective November 7, 2004.
General Authority: SDCL 34-12-13.
Law Implemented: SDCL 34-12-7, 34-12-13.

44:04:01:05. Restrictions on acceptance of patients or residents. A facility shall accept patients or residents in accordance with the following restrictions:

(7) A critical access hospital may provide inpatient acute care up to an annual average length of stay of 96 hours;

Source: 4 SDR 14, effective September 14, 1977; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 15 SDR 155, effective April 20, 1989; 22 SDR 70, effective November 19, 1995; 24 SDR 90, effective January 4, 1998; 26 SDR 96, effective January 23, 2000; 27 SDR 59, effective December 17, 2000.

General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.

44:04:01:08. Modifications. Modifications to standards provided in this article may be approved by the department for an assisted living center with a licensed bed capacity of 16 or less or an adult foster care home if the health and safety of the residents are not jeopardized.

Modifications to the staffing requirements provided in § 44:04:03:02 or 44:04:06:08 may be approved by the department for licensed facilities which are physically combined and jointly operated if:

(1) A hospital or critical access hospital and nursing facility are co-located and the nursing facility has a licensed bed capacity of 16 or less or the hospital has an acute care patient daily census of less than five;

(2) A hospital or a critical access hospital and assisted living center are co-located; or

(3) A nursing facility and assisted living center are co-located.

The health and safety of the patients or residents in either facility must not be jeopardized.

Modifications to the staffing requirements in this article may be approved by the department for a critical access hospital if there are no acute care or swing bed patients present.

Modifications specified by this section may be requested by the health care facility. Any modifications must be approved in writing by the department. The approval letter must specify the modifications permitted and any limitations pertaining to the modifications.

Source: 4 SDR 14, effective September 14, 1977; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 15 SDR 155, effective April 20, 1989; 22 SDR 70, effective November 19, 1995; 26 SDR 96, effective January 23, 2000; 29 SDR 81, effective December 11, 2002.

General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.

44:04:04:15. Transfer agreements. Each specialized hospital and critical access hospital must have in effect a transfer agreement with one or more hospitals to provide services not available

on site. The agreement must provide for an interchange of medical and other necessary information;

Source: Transferred from § 44:04:04:07, 17 SDR 122, effective February 24, 1991; 22 SDR 70, effective November 19, 1995; 26 SDR 96, effective January 23, 2000.

General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.

44:04:05:03. Emergency physician coverage for hospitals and nursing facilities. A patient's or resident's physician shall arrange for the care of the patient or resident by an alternate physician during the physician's unavailability. A hospital must have one or more physicians on duty or call at all times and available to the hospital on-site or by telephone within 20 minutes to give necessary orders or medical care to patients in case of emergency.

Source: SL 1975, ch 16, § 1; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; 27 SDR 59, effective December 17, 2000.

General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.

44:04:05:07. Medical director required. A critical access hospital and a nursing facility must appoint a physician licensed in South Dakota to serve as a medical director. The medical director shall assure physician services are provided only by qualified caregivers.

Source: 22 SDR 70, effective November 19, 1995; 26 SDR 96, effective January 23, 2000.

General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.

44:04:06:08. Nursing service staffing for hospitals. All hospitals must maintain a sufficient number of registered nurses and other qualified nursing personnel on duty at all times to provide supervision of and nursing care for all patients. A registered nurse must be designated as charge nurse for each nursing care unit at all times except that a critical access hospital is required to staff with a registered nurse only when there are acute care patients present. A critical access hospital is required to staff with a licensed nurse when there are only swing bed patients present. Written staffing patterns must be developed for each patient care unit, including surgical and obstetrical suites, emergency services, special care units, and other services. Registered nurses must be in charge of the operating room, function as supervisory nurse in the operating room, be in attendance at all deliveries of obstetrical patients, supervise obstetrical nursing service, and supervise the nursing care of newborn infants.

Source: SL 1975, ch 16, § 1; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; 26 SDR 96, effective January 23, 2000.

General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.

44:04:11:11. Eligibility to offer swing-bed services. A hospital with less than 100 staffed beds may offer swing-bed services after obtaining approval from the department pursuant to

§ 44:04:11:11.01. A hospital with less than 50 staffed beds may not designate more than one-half of its staffed beds as swing beds, but a hospital with less than 50 licensed beds may designate up to one-half of its licensed beds as swing beds. A critical access hospital may have no more than 15 swing beds. A hospital with 50 to 99 staffed beds, inclusive, may not designate more than 10 beds as swing beds. A hospital which subsequently exceeds 99 staffed beds may not offer swing-bed services. For purposes of this section and § 44:04:11:11.01, staffed beds are inpatient beds utilized and staffed for by the hospital, exclusive of beds for newborn, obstetrical delivery, intensive care, coronary care, and any psychiatric or rehabilitation unit excluded from the Medicare prospective payment system, except during a catastrophe, such as a disaster or epidemic, to which the hospital responds.

Source: 14 SDR 81, effective December 10, 1987; 15 SDR 155, effective April 20, 1989; 22 SDR 70, effective November 19, 1995; 26 SDR 96, effective January 23, 2000; 27 SDR 59, effective December 17, 2000; 29 SDR 81, effective December 11, 2002; 30 SDR 84, effective December 4, 2003.

General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.

44:04:11:11.01. Application for approval to offer swing-bed services. A hospital may not offer swing-bed services without first applying in writing to the department for approval. The application must contain the following:

(1) The effective date the swing-bed services will begin;

(2) Designation of the bed category for which the hospital is requesting approval to offer swing-bed services, either a critical access hospital, not more than 49 staffed beds, or greater than 49 staffed beds and fewer than 100 staffed beds;

(3) The number of staffed beds which will be designated as swing beds;

(4) Evidence of the hospital's ability to comply with the provisions of § 44:04:11:12; and

(5) Written assurance that the hospital will operate within the bed category it has designated and will not operate more than the number of swing beds designated on the face of the license.

The department shall denote the number of designated swing beds on the face of the license. A hospital may not change the number of designated swing beds or the designated bed category without first applying to the department for approval in accordance with this section.

Source: 15 SDR 155, effective April 20, 1989; 22 SDR 70, effective November 19, 1995; 26 SDR 96, effective January 23, 2000

General Authority: SDCL 34-12-5, 34-12-13.

Law Implemented: SDCL 34-12-5, 34-12-13.

44:04:11:12. Patient care requirements for swing-bed services. Hospital and critical access hospital swing-bed services must provide nursing and related care services to meet patients' care needs at all times. Patient care services must include at least the following:

(1) Patient rights as stated in §§ 44:04:17:02(1),(5),(6),(7),(8), 44:04:17:03(1), 44:04:17:07, 44:04:17:08(1),(2),(7),(9), 44:04:17:09(3),(4),(5), 44:04:17:12, and 44:04:17:14;

(2) Specialized rehabilitative services needed by patients to improve and maintain functioning. Specialized rehabilitative services may include physical therapy, speech pathology and audiology, and occupational therapy; and the services must be provided by the hospital or arranged for by written agreement with qualified personnel;

(3) Dental services for routine and emergency dental care;

(4) Social services as stated in § 44:04:12:05;

(5) Patient activities as stated in § 44:04:12:02;

(6) Discharge planning services to ensure that patients have a planned program of continuing care which meets post-discharge needs. The hospital must have written policies for the discharge planning process and must comply with § 44:04:04:17; and

(7) Comprehensive assessment to assist with the development of a comprehensive care plan.

Source: 14 SDR 81, effective December 10, 1987; 19 SDR 95, effective January 7, 1993; 22 SDR 70, effective November 19, 1995; 29 SDR 81, effective December 11, 2002; 32 SDR 128, effective January 30, 2006.

General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.

44:04:12:01. Supportive services. Each nursing facility, assisted living center, hospital accepting long-term care patients, and hospital and critical access hospital with swing beds must provide supportive services that comply with §§ 44:04:12:02 to 44:04:12:05, inclusive.

Source: SL 1975, ch 16, § 1; 6 SDR 93, effective July 1, 1980; 14 SDR 81, effective December 10, 1987; 22 SDR 70, effective November 19, 1995; 30 SDR 84, effective December 4, 2003.

General Authority: SDCL 34-12-13.

Law Implemented: SDCL 34-12-13.

APPENDIX D

CMS Interpretive Guidelines for CAH Location and Relocation

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-06-04

DATE: **November 14, 2005**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: Location and Relocation of Critical Access Hospitals (CAHs) and Relocation of Necessary Provider CAHs

Letter Summary

This letter provides guidance for the implementation of new regulations (Changes to Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates (CMS-1500-F), 70 Fed. Reg. 47278, 47490 (Aug. 12, 2005)) regarding the location and relocation of CAHs, including CAHs with a grandfathered necessary provider designation.

Items addressed include:

- Criteria for determining mountainous terrain;
- Revised definitions of primary and secondary roads;
- Criteria and procedures to be used to determine if a provider remains essentially the same provider and serves the same community after relocation;
- Documentation to be included in a letter of attestation from a provider that wishes to relocate and maintain its provider agreement;
- Criteria to be used to determine compliance with the 75 percent rules; and
- Requirement to have an effective date prior to January 1, 2006, to participate in Medicare as a CAH using a grandfathered necessary provider designation.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), enacted on December 8, 2003, contained a number of modifications to the CAH statutory requirements including a new provision that eliminated the use of State-issued necessary provider designations (issued to allow participation of CAHs that do not meet the Condition of Participation requirement at 42 CFR §485.610(c) requiring a CAH to be located 35 miles from a hospital or another CAH or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive). The MMA stipulates that the necessary provider designations would no longer be issued on or after January 1, 2006.

The MMA also allows grandfathering for CAHs that were already certified via a necessary provider designation prior to January 1, 2006. The CAH must have met all federal requirements as a CAH with an effective date for Medicare participation as a CAH prior to January 1, 2006, to receive or continue their necessary provider status after January 1, 2006.

Continued certification following a relocation of a currently-certified facility has traditionally been decided by Centers for Medicare & Medicaid Services (CMS) Regional Offices (ROs) on a case-by-case basis. We do not intend to change that policy. The new regulation and its interpretive guidelines establish a methodology to be used by all ROs to provide a fair and consistent determination as to whether a CAH remains essentially the same provider serving the same community after relocation and therefore may continue to operate under the same Medicare provider agreement.

Relocation of Any CAH

If any CAH plans to relocate to a new location, CMS would need to determine if this would be a relocation of the current provider or a cessation of business at one location and establishment of a new business at another location. In the event of relocation, the CAH must ensure to the RO that it is functioning as essentially the same provider serving the same community in order to maintain and operate under the same provider agreement. A provider changing locations is a closure of the old facility if the original community can no longer be expected to be served at the new location. The distance moved from the old location will be considered but will not be the sole determining factor in granting the relocation of a CAH under the same provider agreement. For example, the relocation of a CAH a relatively short distance may greatly affect the community served. In other areas with vast distances between providers, a large distance may have little effect on the community served. Clearly, mileage alone is not valid as a single criterion but it may be used if it clearly demonstrates that the provider has left the original community.

The attached interpretive guidelines address the criteria used by the RO to determine if a CAH that relocates continues to be essentially the same provider serving the same community so that the same provider agreement would continue to apply to the CAH at the new location. The RO will evaluate the documentation provided by the CAH in its letters of attestation in order to make this determination.

In all cases of relocation, the CAH must continue to meet all Conditions of Participation found at 42 CFR §485 subpart F, including location in a rural area as found at 42 CFR §485.610. A survey of the CAH should be conducted in the new location to determine compliance with the CAH CoPs, including the Life Safety Code requirements.

Relocation of a CAH with a Necessary Provider Designation

If the CAH is operating under a necessary provider designation that exempts the distance from other providers, there are additional requirements to determine if the grandfathered designations can follow the CAH to a different site.

CMS defines the expiration of the necessary provider designations to mean that a CAH must be certified with a Medicare effective date prior to January 1, 2006, in order to fall within the timeframe for having its necessary provider designation grandfathered. In addition, CMS also stipulates that the designations do not automatically follow the provider if the facility relocates to a different location.

The attached guidelines will be used by the RO to determine if the grandfathered necessary provider designation will follow the CAH to a new location.

If the CAH relocation results in the CAH not remaining essentially the same provider or in the cessation of furnishing services to the same community, CMS would not consider this to be a relocation but would instead consider such a scenario to be a cessation of business at one location and establishment of a new business at another location. Cessation of business is a basis for termination of the provider agreement under 42 CFR §489. If the proposed move constitutes a cessation of business, the RO may assist the provider in obtaining a new provider agreement as a CAH or another provider type, as appropriate. Furthermore, in such a situation, CMS regulations require the provider to give advanced notice to CMS and the public regarding its intent to stop providing medical services to the community.

If you have any questions that cannot be answered by the appropriate RO staff, please contact Marjorie E. Eddinger at 410-786-0375 or via email at marjorie.eddinger@cms.hhs.gov.

Effective Date: The SA should disseminate this information within 30 days of the date of the memorandum.

Training: This clarification should be shared with all survey and certification staff, surveyors, their managers, and the State/RO training coordinator.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management (G-5)

Attachment

C-0165

§485.610(c) Standard: Location Relative to Other Facilities or Necessary Provider Certification

The CAH is located more than a 35-mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital or another CAH, or *before January 1, 2006, the CAH is designated by the State as being a necessary provider of health care services to residents in the area. A CAH that is designated as a necessary provider as of January 1, 2006, will maintain its necessary provider designation after January 1, 2006.*

Interpretive Guidelines §485.610(c)

Mountainous Terrain. *There are many locations that are called mountains that are not considered mountainous terrain. These may be foothills or ancient worn down mountains that do not have the fundamental characteristics of mountainous terrain. It is not uncommon for roads through mountainous areas to travel through valleys, over areas of high elevation, over high plateaus and other areas that do not have the characteristics of "mountainous terrain." Being located at the foot of a mountain, or being able to view mountains from the CAH does not, in and of itself, mean the CAH is located in "mountainous terrain."*

Slope and ruggedness of terrain, together with absolute altitude determine many of the fundamental characteristics of mountainous terrain. For the purposes of this regulation, to be considered located in mountainous terrain the CAH must comply with all of the following criteria:

- *The CAH must be located in a mountain range (being located within a mountain range, in and of itself, does not mean a CAH is located in "mountainous terrain");*

- *The CAH, or portions of the road to the nearest hospital or CAH, must be located at an elevation above 3000 feet and the travel route is regularly or seasonally subjected to weather-related hazardous driving conditions, such as poor visibility, slippery roads, or snow-covered roads resulting in slow driving speeds, required use of snow chains, or road closures. (Being located at a high elevation, in and of itself, does not constitute "mountainous terrain.");*

- *The roads on the travel route must be considered as traveling through mountainous terrain by the State Department of Transportation;*

- *The travel roads consist of extensive sections of roads with grades greater than 5 percent, and/or consist of continuous abrupt and frequent changes in elevation or direction. (These roads typically have frequent areas of low speed limits (15-25 mph) and many warning signs denoting sharp curves, steep grades, and frequent changes in direction. Roads through mountainous terrain usually display frequent benching and side hill excavation); and*

- *The safe speed limit on the travel route to the nearest hospital/CAH is less than 45 mph.*

When calculating the mountainous terrain travel distance to the nearest hospital/CAH, subtract the total of the distances represented by those sections of the travel route that are not considered "mountainous terrain." Travel routes that are not considered mountainous terrain include:

- *Those sections of the travel route of at least 1 mile in length, where the safe driving speed limit is 45 mph or greater, do not count toward the 15- mile mountainous terrain distance; and*

- *Those sections of the travel route of at least 1 mile in length, where the roads on the travel route have grades less than 5 percent and/or do not have frequent, abrupt changes in direction or elevation are not considered mountainous terrain and do not count toward the 15-mile mountainous terrain distance.*

***Definition of a Primary Road**. A primary road is an interstate highway, a U.S. highway, an expressway, an intrastate highway, a State-divided highway with two or more lanes each way, or any road with at least two contiguous miles with a speed limit of 45 mph or greater.*

***Definition of a Secondary Road**. A secondary road is any state or local road, paved or unpaved, that does not meet the definition of "primary road" as herein stated.*

A CAH meets the 15- mile secondary road distance requirement when the CAH is located less than 35 miles, but more than 15 miles, from a hospital or another CAH and at least one section of the shortest route to the nearest hospital or CAH consists of more than 15 miles of continuous uninterrupted secondary roads.

Travel distance is measured using the driving distance on the shortest possible route on federal, state, or local roads. The distance requirement is not limited to the State boundaries. The distance requirement applies to ANY hospital or CAH, regardless of State boundary lines.

***Issuance of Necessary Provider Designations for the Location Requirement.** States will no longer be allowed to designate a CAH as a necessary provider after January 1, 2006. A CAH that has met all federal requirements as a CAH, has an effective date for Medicare participation as a CAH prior to January 1, 2006, has been certified as a CAH based on a necessary provider designation made prior to January 1, 2006, and that continues to provide services based on the same criteria that originally qualified the CAH to be a necessary provider, may continue to maintain their necessary provider status after January 1, 2006.*

The regulation that allows a CAH's necessary provider designation to be grandfathered after January 1, 2006, does not apply where the CAH is no longer the same facility due to relocation, voluntary or involuntary termination of the provider agreement, or cessation of business. The necessary provider designation automatically ends if the Medicare provider agreement with that CAH is terminated, either voluntarily or involuntarily.

***Maintenance of Necessary Provider Designation.** Any CAH that is designated as a necessary provider in its State rural health plan prior to January 1, 2006, and certified by Medicare with an effective date prior to January 1, 2006, can be grandfathered as long as the CAH continues to provide services based on the same criteria that originally qualified the CAH to be designated as a necessary provider. If the grandfathered CAH relocates the facility, the CAH must continue to meet the criteria that originally qualified them for designation as a necessary provider.*

The State Agencies and CMS Regional Offices will closely monitor any such relocation to ensure that the CAH continues to provide services based on the criteria that originally qualified the CAH to be designated as a necessary provider.

***Collocation Issues Using a Necessary Provider Designation**. CMS does not view a CAH that is collocated with a hospital or another CAH as a "necessary provider" of services. A CAH with a necessary provider designation cannot become collocated with a hospital or another CAH and maintain its grandfathered status. The collocation of a CAH with a hospital or another CAH would void the state's previous designation of the CAH as a necessary provider.*

Survey Procedures §485.610(c)

- *The SA will determine that a CAH meets the basic location requirement prior to scheduling the survey in the new location. The appropriate RO will reverify the location requirement prior to approving the CAH in the new location.*

- *Use maps, Department of Transportation information, information from the United States Geodesic Service, and/or GIS programming in order to evaluate distances, types of roads, terrain, speed limits, and driving conditions.*

- *Determine the shortest driving route between the CAH and the nearest hospital or another CAH. Actually driving the road(s) on the shortest route may be used to document speed limits, terrain, curves, distances that can be excluded, driving conditions, and total distance.*

C-0166

§485.610(d) Standard: Relocation of CAHs with a necessary provider designation.

A CAH that has a necessary provider designation from the State that was in effect prior to January 1, 2006, and relocates its facility after January 1, 2006, can continue to meet the location requirement of paragraph (c) of this section based on the necessary provider designation only if the relocated facility meets the requirements as specified in paragraph (d)(1) of this section.

(1) If a necessary provider CAH relocates its facility and begins providing services in a new location, the CAH can continue to meet the location requirement of paragraph (c) of this section based on the necessary provider designation only if the CAH in its new location--

> ***(i) Serves at least 75 percent of the same service area that it served prior to its relocation;***
>
> ***(ii) Provides at least 75 percent of the same services that it provided prior to the relocation; and***
>
> ***(iii) Is staffed by 75 percent of the same staff (including medical staff, contracted staff, and employees) that were on staff at the original location.***

(2) If a CAH that has been designated as a necessary provider by the State begins providing services at another location after January 1, 2006, and does not meet the requirements in paragraph (d)(1) of this section, the action will be considered a cessation of business as described in §489.52(b)(3).

Interpretive Guidelines §485.610(d)

These guidelines are meant to be applied to any relocated CAH, with or without a necessary provider designation. Any CAH may relocate at any time if the CAH continues to be essentially the same provider serving the same community, and meets all the Conditions of Participation at 42 CFR Part 485, Subpart F.

The relocation criteria include specific criteria for a CAH with a grandfathered necessary provider designation that plans to relocate and that wishes to maintain its necessary provider designation after the relocation. At its new location, a CAH with a necessary provider designation must continue to be essentially the same provider, must continue to meet the same criteria under which it was originally designated by its State as a necessary provider, must comply with the requirements at §485.610(d) as herein described, and must comply with all the Conditions of Participation at 42 CFR §485 subpart F.

CAHs that construct a new facility will be considered to have relocated. The CMS Regional Office will determine if the CAH meets the requirements for relocation on a case-by-case basis. In all cases of relocation, the CAH must meet all of the CoPs found at 42 CFR Part 485, Subpart F, including location in a rural area as required at §485.610. (Note: The CMS Regional Office can provide guidance on questions regarding rural vs urban status.

***Retention of the Medicare Provider Agreement after a Provider Relocation**. In order for any provider to relocate and maintain its provider agreement from the previous location, a provider must be essentially the same provider serving the same community at the new location.*

Criteria that are used by CMS to determine if any provider continues to be essentially the same provider at a new location as it was at its original location include:

- *The provider remains in the same State and complies with the same State licensure requirements;*
- *The provider remains the same type of Medicare provider after relocation;*
- *The provider maintains at least 75 percent of the same medical staff, nursing staff and other employees, and contracted personnel (contracted personnel includes all personnel who regularly work 20 or more hours a week at the provider, whether they are directly contracted by the provider or whether they are employees of a contractor.);*
- *The provider retains the same governing body, or person(s) legally responsible for the provider, after the relocation;*
- *The provider maintains essentially the same policies and procedures such as nursing, infection control, pharmacy, patient care, etc.;*

- *The provider maintains essentially the same Medical Staff bylaws, policies and procedures;*

- *At least 75 percent of the services offered by the provider during the last year at the original location continue to be offered at the new location;*

- *The distance the provider moves from the original site;*

- *The provider continues to serve at least 75 percent of the original community at its new location;*

- *The provider complies with all Federal requirements, including CMS requirements and regulations at the new location; and*

- *CMS may use any other information, determined by CMS to be necessary, to determine if a provider continues to be essentially the same provider, under the same provider agreement, after relocation.*

CAH Relocation in General. *In the event of relocation, any CAH, with or without a necessary provider designation, must ensure that it is functioning as essentially the same provider and continues to serve the same community in order to operate under the same provider agreement. A provider that is changing location is considered to have closed the old facility if the original community or service area can no longer be expected to be served at the new location. The intent of the CAH program is to keep hospital-level services in rural communities, thereby ensuring access to care. CMS allows any CAH, including a CAH with a grandfathered necessary provider designation, to relocate its facility as long as the CAH remains essentially the same provider and continues to ensure access to care in the same community.*

The distance of the moved CAH from its old location will be considered, but will not be the sole determining factor in granting the relocation of a CAH under the same provider agreement. There may be situations where the CAH relocation is so far removed from the originally approved site that we would conclude that this is a different provider. If, for example, the CAH serves a different community, offers substantially different services to the community, or employs substantially different employees to provide those services, we would conclude that this is a different provider.

Relocation of a CAH with a Grandfathered Necessary Provider Designation*. The necessary provider designation does not automatically follow the provider if the facility relocates to a different location. In order to maintain its necessary provider designation after relocation, a CAH with a grandfathered necessary provider designation must have an effective date for Medicare participation as a CAH prior to January 1, 2006, and continue to meet the same criteria it originally met to be designated as a necessary provider by the State and must meet the requirements of §485.610(d).*

Those criteria used to qualify a CAH as a necessary provider were established by each State in the State Medicare Rural Hospital Flexibility Plan (MRHFP). The State plan identified those CAHs that provided essential services to a particular patient community in the event that the facility did not meet the required distance requirement from the nearest hospital or CAH. All the State criteria are different but share similarities and all define a necessary provider relative to

the facility location. It therefore becomes crucial to define whether the necessary provider designation remains pertinent in defining the facility in a different location in the event the CAH moves. In order to assess the impact on its necessary provider designation status and to obtain a letter of assurance regarding its continued compliance with State necessary provider criteria, a CAH with a necessary provider designation should inform and consult with their State Office of Rural Health early in the planning stages of a proposed relocation. Prior to a CAH with a grandfathered necessary provider designation relocating, its State Office of Rural Health must confirm whether the CAH's necessary provider designation remains pertinent and provide a letter of assurance to CMS.

***75 Percent Criteria**. CMS may allow a CAH with necessary provider certification to replace its facility at any time and to maintain its necessary provider designation provided it complies with each of the 75 percent criteria. The 75 percent criteria will assist in ensuring continued access to care in the community for which any CAH was originally certified. The relocated CAH must meet all the defining criteria listed under each 75 percent criteria in order to maintain its necessary provider designation after a relocation.*

***75 percent Community Served.** The relocated CAH must comply with all of the following defining criteria in order to meet "75 percent community served."*

- *At least 75 percent of the community prior to the CAH's relocation must continue to utilize the CAH after the relocation. One factor to consider is the number of people in the original community that will seek healthcare at a different provider after the CAH relocates.*

- *At least 75 percent of the same people in various demographic groups within the community must continue to be served at the new location. At a minimum this includes at least 75 percent of the original Medicaid and Medicare beneficiaries, and at least 75 percent of the original families with incomes at less than 100 percent of the Federal poverty level.*

- *At least 75 percent of the patients served at the new location reside in the same zip code areas served at the CAH's previous location.*

- *Taken as a whole, 75 percent of the people in the CAH's original service area continue to have the same access to care at the CAH as measured by whether they have equal or less travel distance to come to the CAH at the new location.*

- *CMS will use any other criteria or information it deems appropriate to evaluate whether the CAH continues to serve at least 75 percent of the original population.*

***Providing at Least 75 percent of the Same Services**. The relocated CAH must meet all the following defining criteria in order to meet "providing at least 75 percent of the same services."*

- *At least 75 percent of the total services provided by the CAH during the last year at its original location must continue to be offered at its new location for at least one year. For example, the CAH offered 10 services during the previous year. After relocation the CAH offers all 10 services and adds 3 new services. They have retained 100 percent of their services and added new services. If they drop 3 services, even though they add 3 new and different services, they have not maintained 75 percent.*

- *At least 75 percent of the billing codes and the volume for inpatient and outpatient services provided by the CAH during the last year prior to the relocation must remain the same for at least one year after the move. CMS will evaluate both the type of services offered and the volume of each type of service offered, as appropriate.*

Providing Services Using 75 percent of the Same Staff (including medical staff, contracted staff and direct employees). *The relocated CAH must meet all of the following defining criteria in order to meet "providing services using 75 percent of the same staff."*

- *75 percent of the members of the CAH's medical staff, 75 percent of its direct employees, and 75 percent of its contract staff that were at the CAH during the previous year prior to relocation, remain on staff for the first year after the relocation. Contracted staff includes all personnel who regularly work 20 or more hours a week at the CAH, whether they are directly contracted by the CAH or whether they are employees of a contractor.*

- *To address the employee criterion, the CAH must provide a list of medical staff, contract staff, and employees before and after the move.*

Cessation of Business.

Under existing CMS policy, if the CAH relocation results in the CAH not remaining essentially the same provider or in the cessation of furnishing services to the same community, we would not consider this to be a relocation, but instead would consider such a scenario to be a cessation of business at one location and establishment of a new business at another location. Cessation of business is a basis for voluntary termination of the provider agreement under 42 CFR Part 489. If the proposed move constitutes a cessation of business, the RO may assist the provider in obtaining an agreement to participate under a new provider agreement.

There is no appeals process for a voluntary termination. Under CMS policies, the cessation of business by a CAH automatically terminates the CAH provider agreement regardless of whether the designation was obtained through a necessary provider determination or not.

Letter of Attestation*.*

Prior to any relocation of a CAH, the CAH must send a letter of intent to the SA and to the RO. The CAH should send the letter early in the planning stage of its relocation and prior to spending or obligating significant funds and resources. The letter should state that the CAH plans to relocate and must attest that it will continue to be essentially the same provider serving the same community but at a new location.

The Letter of Attestation must:

- *Include addresses, both the present location and the future location;*
- *Provide documentation that supports that it will continue to be essentially the same provider at the new location as herein described;*
- *Include the travel distance from the current location to the future location;*
- *Provide the names, addresses, and travel distances to all hospitals and CAHs that share and surround the community at the current and future locations;*
- *Provide documentation to address all criteria previously discussed in "Retention of the Medicare Provider Agreement after Provider Relocation";*
- *Provide a time table for the relocation;*
- *Any CAH with a grandfathered necessary provider designation that is planning to relocate and that wishes to maintain its designation as a necessary provider must provide documentation to support the CAH attestation that it will meet the requirements in §485.610(d)(1) in every area as herein stated (75 percent community served, services provided, and staff. The documentation must include references and sources for numbers and statistics used);*
- *Any grandfathered CAH planning to relocate that wishes to maintain its designation as a necessary provider must provide documentation that demonstrates that the CAH will continue to meet the same criteria that was originally used by the State for its designation as a necessary provider. Additionally, the CAH must include a letter of assurance from the State Office of Rural Health (or the agency in the State that is authorized to designate CAHs) that it has made a preliminary determination that the CAH will continue to meet the original criteria for its designation as a necessary provider at its new location.*
- *All documentation must identify source(s) and references used by the CAH to develop statistics, numbers, and other attestation requirements;*

The RO will evaluate the letter of attestation and documentation provided by the CAH including any other information that the RO deems appropriate in its comparison of the CAH at its current and future locations. The RO will advise the CAH of any additional information that may be needed for evaluation. The RO will advise the CAH of the results of its preliminary evaluation. ***The final determination will not occur until after the CAH relocates****.*

Construction and Relocation Phase*. During the construction and relocation the CAH must notify the SA and the RO of any changes, other than minor changes, that are identified by the CAH that change its letter of self attestation that it will be essentially the same provider serving the same community at the identified location and that it will be in compliance with §485.610(d).*

After Relocation*. Once the relocation is complete the CAH must attest that it remains essentially the same provider serving the same community in its new location and whether the information provided with its earlier attestation remain the same. The CAH must address any changes in its*

previous attestation letter and must provide documentation to demonstrate that it is essentially the same provider serving the same community at the new location and, for a CAH with a necessary provider designation, that it meets all the requirements in §485.610(d) at its new location. Additionally, a CAH with a grandfathered necessary provider designation must provide a letter of determination from its State Office of Rural Health (dated after the relocation is complete) advising CMS as to whether or not the relocated CAH continues to meet the original criteria for its designation as a necessary provider now that the CAH has completed its move to the new location.

Once the CAH has completed its relocation and has forwarded all required and requested documentation to the RO, the RO will make its determination of the CAH's status. The RO will advise the CAH of any additional information that is needed to make the determination. After completing its evaluation and making its determination, the RO will notify the CAH in a letter as to whether the CAH will retain the same provider agreement and, as applicable, whether the CAH can retain its necessary provider designation.

In addition to the determination made immediately after a CAH's relocation, and at the RO's discretion, the RO may conduct a review one year after a CAH's relocation to determine that a relocated CAH meets the relocation criteria.

Survey Procedures §485.610(d)

- *The RO will evaluate the letter of attestation and documentation provided by the CAH including any other information that the RO deems appropriate in its comparison of the CAH at the old and new sites. The RO will determine whether the CAH remains essentially the same provider serving the same community after relocation and may continue to operate under the same Medicare provider agreement. The RO will communicate with the CAH, the State Office of Rural Health, and the SA, as it deems necessary, to conduct its determination.*

- *Additionally, for the relocation of a CAH with a necessary provider designation, theRO will determine whether the CAH complies with §485.610(d) after a relocation.*

- *In order to determine if a relocated CAH with a grandfathered necessary provider designation continues to meet the original criteria for its designation as a necessary provider at its new location, the RO must receive a letter of assurance from the CAH's State Office of Rural Health.*

- *A survey of the CAH should be conducted in the new location to determine compliance with all CoPs, including Life Safety Code requirements, and to verify the information in the letter of attestation.*

PART 415—SERVICES FURNISHED BY PHYSICIANS IN PROVIDERS, SUPERVISING PHYSICIANS IN TEACHING SETTINGS, AND RESIDENTS IN CERTAIN SETTINGS

■ D. Part 415 is amended as follows:
■ 1. The authority citation for Part 415 continued to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 415.55 [Amended]

■ 2. In § 415.55(a)(5), the reference ''§ 413.86'' is removed and the reference ''§§ 413.75 through 413.83'' is added in its place.

§ 415.70 [Amended]

■ 3. In § 415.70(a)(2), the reference ''§ 413.86'' is removed and the reference ''§§ 413.75 through 413. 83'' is added in its place.

§ 415.102 [Amended]

■ 4. In § 415.102(c)(1), the reference ''§ 413.86'' is removed and the reference ''§§ 413.75 through 413.83'' is added in its place.

§ 415.150 [Amended]

■ 5. In § 415.150(b), the reference ''§ 413.86'' is removed and the phrase ''§§ 413.75 through 413.83'' is added in its place.

§ 415.152 [Amended]

■ 6. In § 415.152—
■ a. In paragraph (2) of the definition of ''Approved graduate medical education program'', the reference ''§ 413.86(b)'' is removed and the reference ''§ 413.75(b)'' is added in its place.
■ b. In the definition of ''Teaching setting'', the reference ''§ 413.86,'' is removed and the reference ''§§ 413.75 through 413.83,'' is added in its place.

§ 415.160 [Amended]

■ 7. In § 415.160—
■ a. In paragraph (c)(2), the reference ''§ 413.86'' is removed and the reference ''§ 413.78'' is added in its place.
■ b. In paragraph (d)(2), the reference ''§ 413.86'' is removed and the reference ''§§ 413.75 through 413.83'' is added in its place.

§ 415.174 [Amended]

■ 8. In § 415.174(a)(1), the reference ''§ 413.86.'' is removed and the phrase ''§§ 413.75 through 413.83.'' is added in its place.

§ 415.200 [Amended]

■ 9. In § 415.200(a), the reference ''§ 413.86'' is removed and the reference ''§§ 413.75 through 413.83'' is added in its place.

§ 415.204 [Amended]

■ 10. In § 415.204(a)(2), the reference ''§ 413.86'' is removed and the reference ''§§ 413.75 through 413.83'' is added in its place.

§ 415.206 [Amended]

■ 11. In § 415.206(a), the reference ''§ 413.86(f)(1)(iii)'' is removed and the reference ''§ 413.78'' is added in its place.

§ 415.208 [Amended]

■ 12. In § 415.208—
■ a. In paragraph (b)(1), the reference ''§ 413.86'' is removed and the reference ''§§ 413.75 through 413.83'' is added in its place.
■ b. In paragraph (b)(4), the reference ''§ 413.86'' is removed and the reference ''§§ 413.75 through 413. 83'' is added in its place.

PART 419—PROSPECTIVE PAYMENT SYSTEM FOR OUTPATIENT DEPARTMENT SERVICES

■ F. Part 419 is amended as follows:
■ 1. The authority citation for part 419 continues to read as follows:

Authority: Secs. 1102, 1833(t), and 1871 of the Social Security Act (42 U.S.C. 1302, 1395l(t), and 1395hh).

§ 419.2 [Amended]

■ 2. In § 419.2—
■ a. In paragraph (c)(1), the reference ''§ 413.86'' is removed and the reference ''§§ 413.75 through 413.83'' is added in its place.
■ b. In paragraph (c)(6), the reference ''§ 413.80(b)'' is removed and the reference ''§ 413.89(b)'' is added in its place.

PART 422—SPECIAL RULES FOR SERVICES FURNISHED BY NONCONTRACT PROVIDERS

■ G. Part 422 is amended as follows:
■ 1. The authority citation of part 422 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

§ 422.214 [Amended]

■ 2. In § 422.214—
■ a. In paragraph (b), the phrase ''§§ 412.105(g) and 413.86(d))'' is removed and the phrase ''§§ 412.105(g) and 413.76))'' is added in its place.
■ b. In paragraph (b), the phrase ''Section 413.86 (d)'' is removed and the phrase ''Section 413.76'' is added in its place.

§ 422.216 [Amended]

■ 3. In § 422.216(a)(4), the reference ''§§ 412.105(g) and 413.86(d)'' is removed and the reference ''§§ 412.105(g) and 413.76'' is added in its place.

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ G. Part 485 is amended as follows:
■ 1. The authority citation for Part 485 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh.

■ 2. Section 485.610 is amended by—
■ a. In paragraph (b)(1)(i), removing the reference ''§ 412.62(f)'' and adding in its place the reference ''§ 412.64(b), excluding paragraph (b)(3).''
■ b. Removing paragraph (b)(1)(ii) and redesignating paragraph (b)(1)(iii) as paragraph (b)(1)(ii).
■ c. Adding a new paragraph (d).

The revisions and additions read as follows:

§ 485.610 Condition of participation: Status and location.

* * * * *

(d) *Standard: Relocation of CAHs with a necessary provider designation.* A CAH that has a necessary provider designation from the State that was in effect prior to January 1, 2006, and relocates its facility after January 1, 2006, can continue to meet the location requirement of paragraph (c) of this section based on the necessary provider designation only if the relocated facility meets the requirements as specified in paragraph (d)(1) of this section.

(1) If a necessary provider CAH relocates its facility and begins providing services in a new location, the CAH can continue to meet the location requirement of paragraph (c) of this section based on the necessary provider designation only if the CAH in its new location—

(i) Serves at least 75 percent of the same service area that it served prior to its relocation;

(ii) Provides at least 75 percent of the same services that it provided prior to the relocation; and

(iii) Is staffed by 75 percent of the same staff (including medical staff, contracted staff, and employees) that were on staff at the original location.

(2) If a CAH that has been designated as a necessary provider by the State begins providing services at another location after January 1, 2006, and does not meet the requirements in paragraph (d)(1) of this section, the action will be considered a cessation of business as described in § 489.52(b)(3).